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Fig 1

A

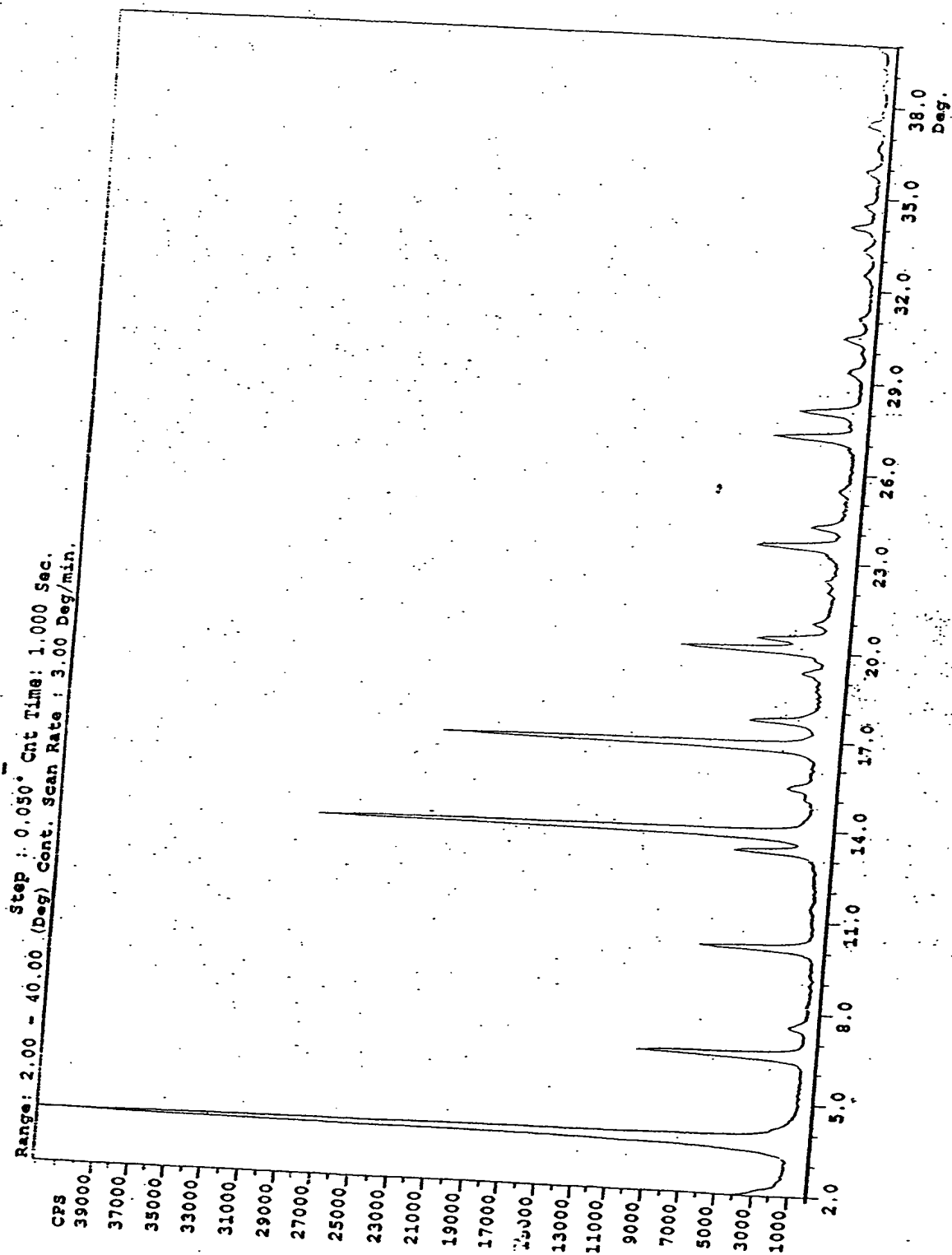


Fig. 2 C

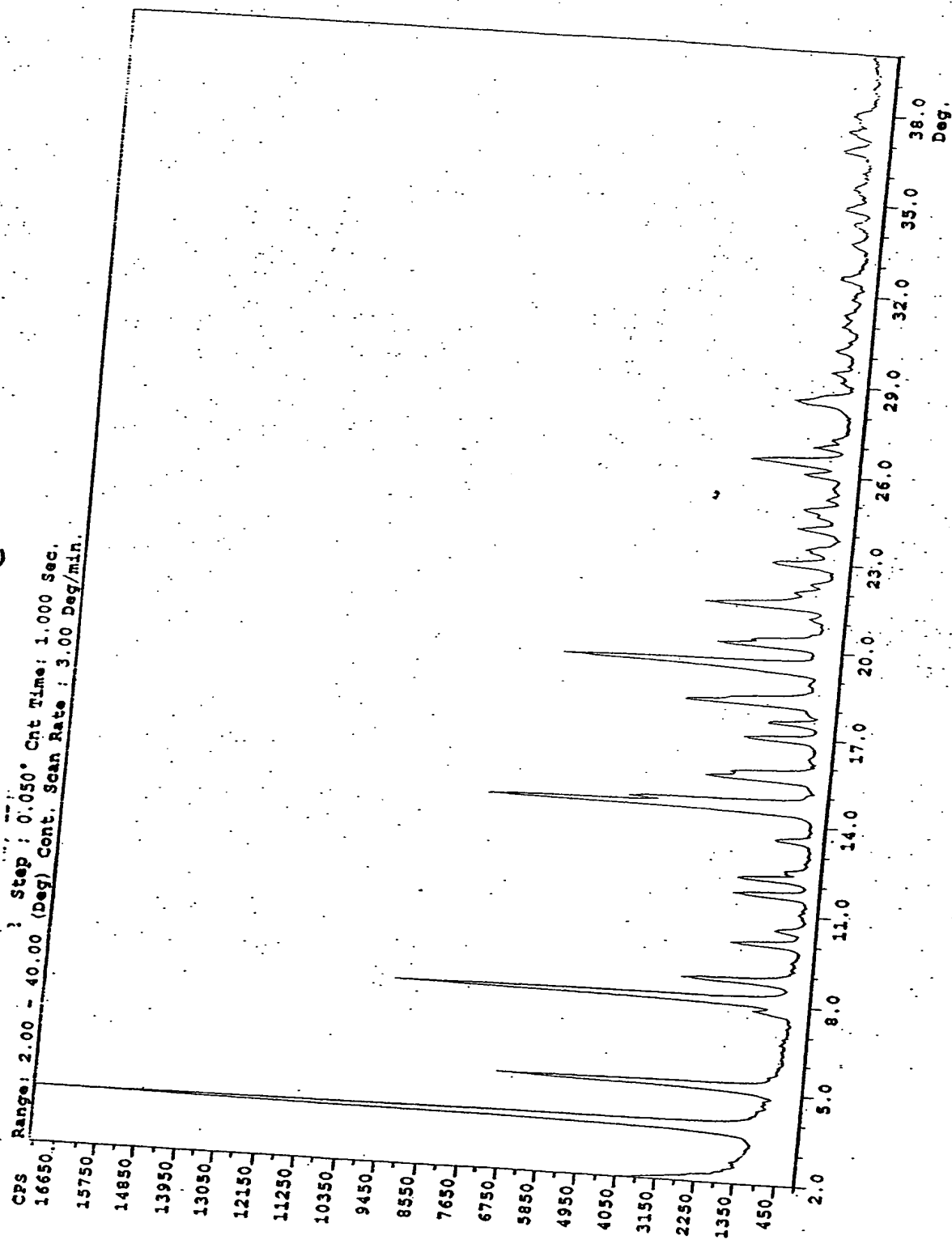
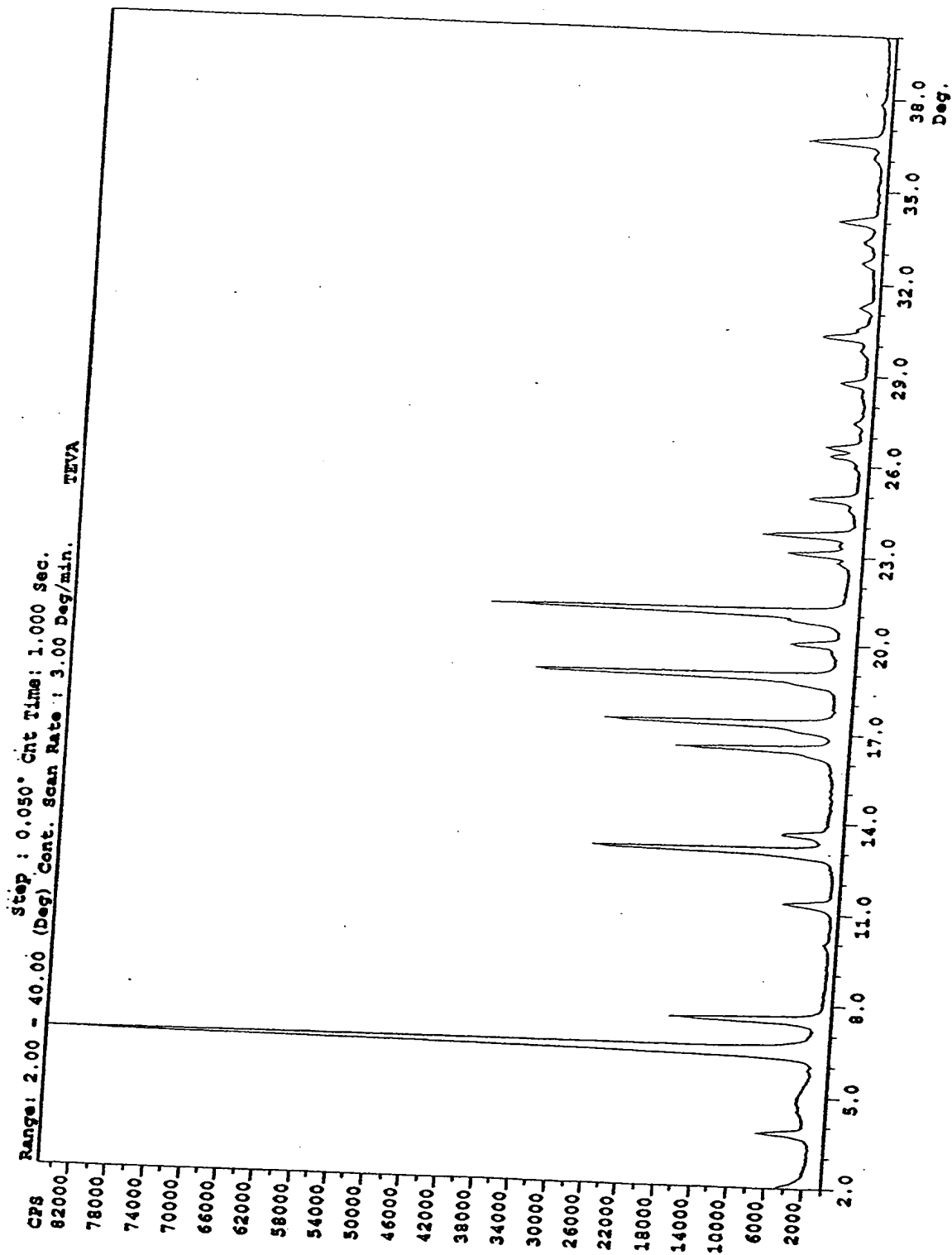


Fig 3 D



Range: 2.00 - 40.00, Step: 0.050, Cnt Time: 1.000 Sec.  
CPS 12350 12250 11550 10850 10150 9450 8750 8050 7350 6650 5950 5250 4550 3850 3150 2450 1750 1050 350

2.0 5.0 8.0 11.0 14.0 17.0 20.0 23.0 26.0 29.0 32.0 35.0 38.0  
Deg.

TEVA

TEVA

Fig. 5

F

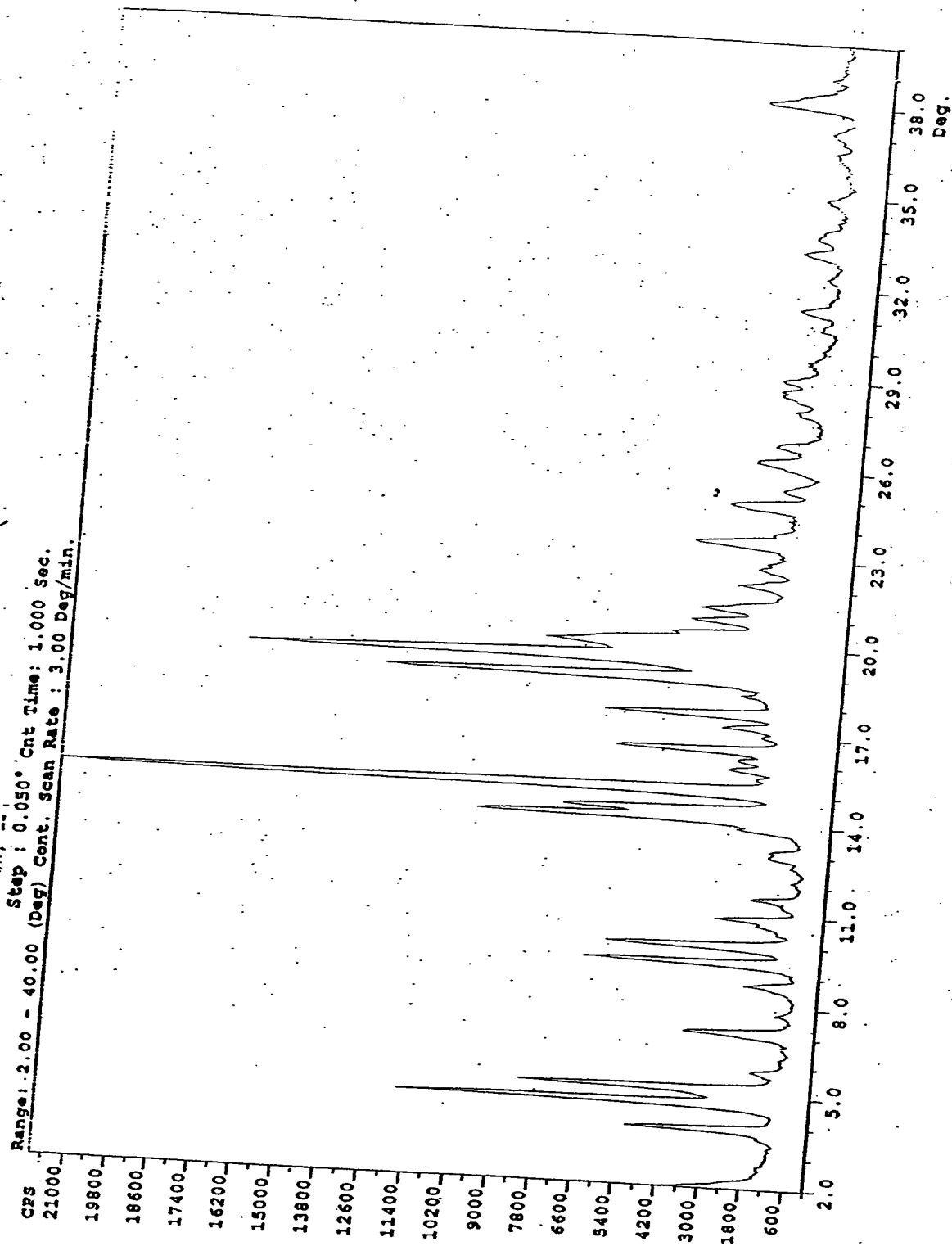


Fig. 6

G

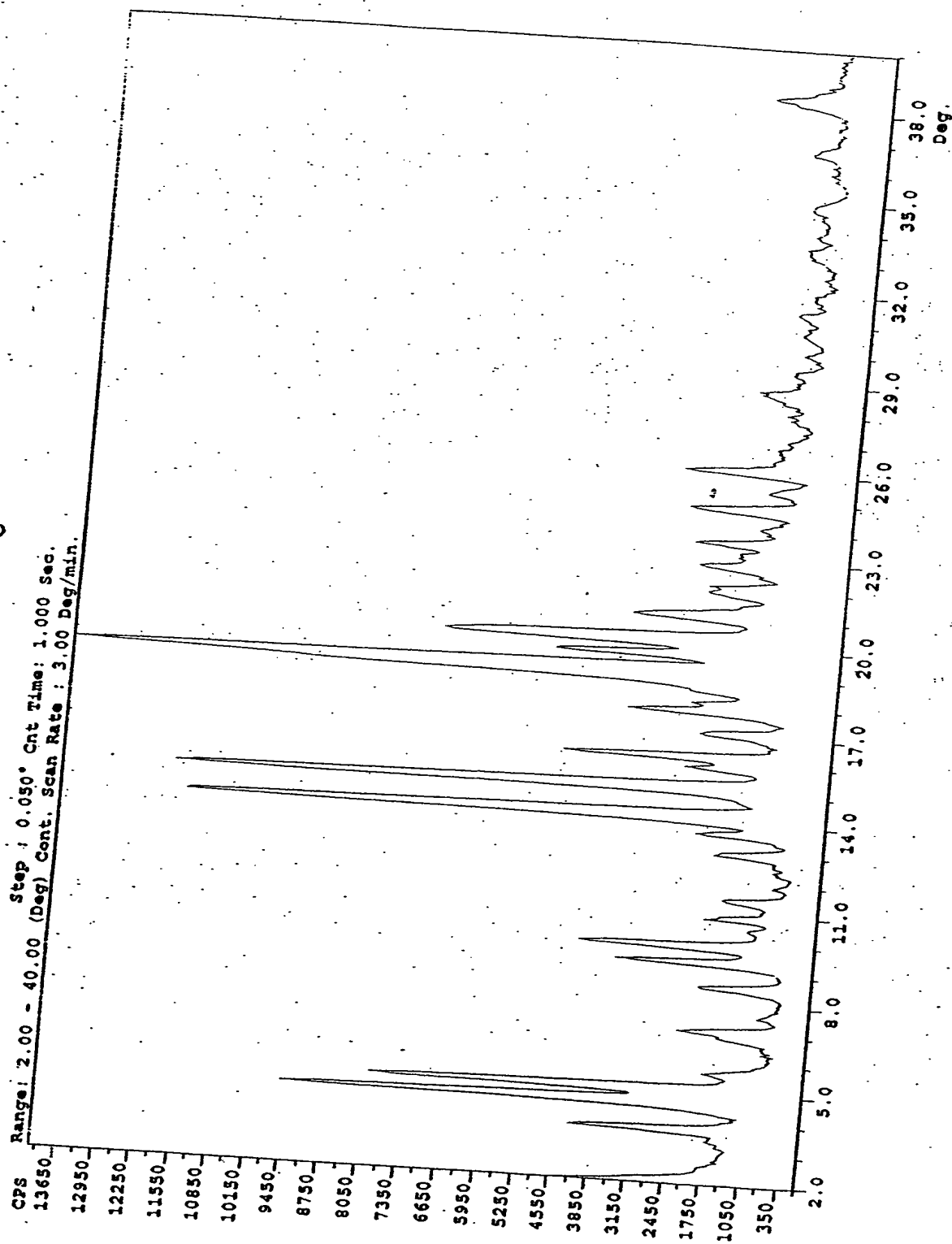


Fig 7 I

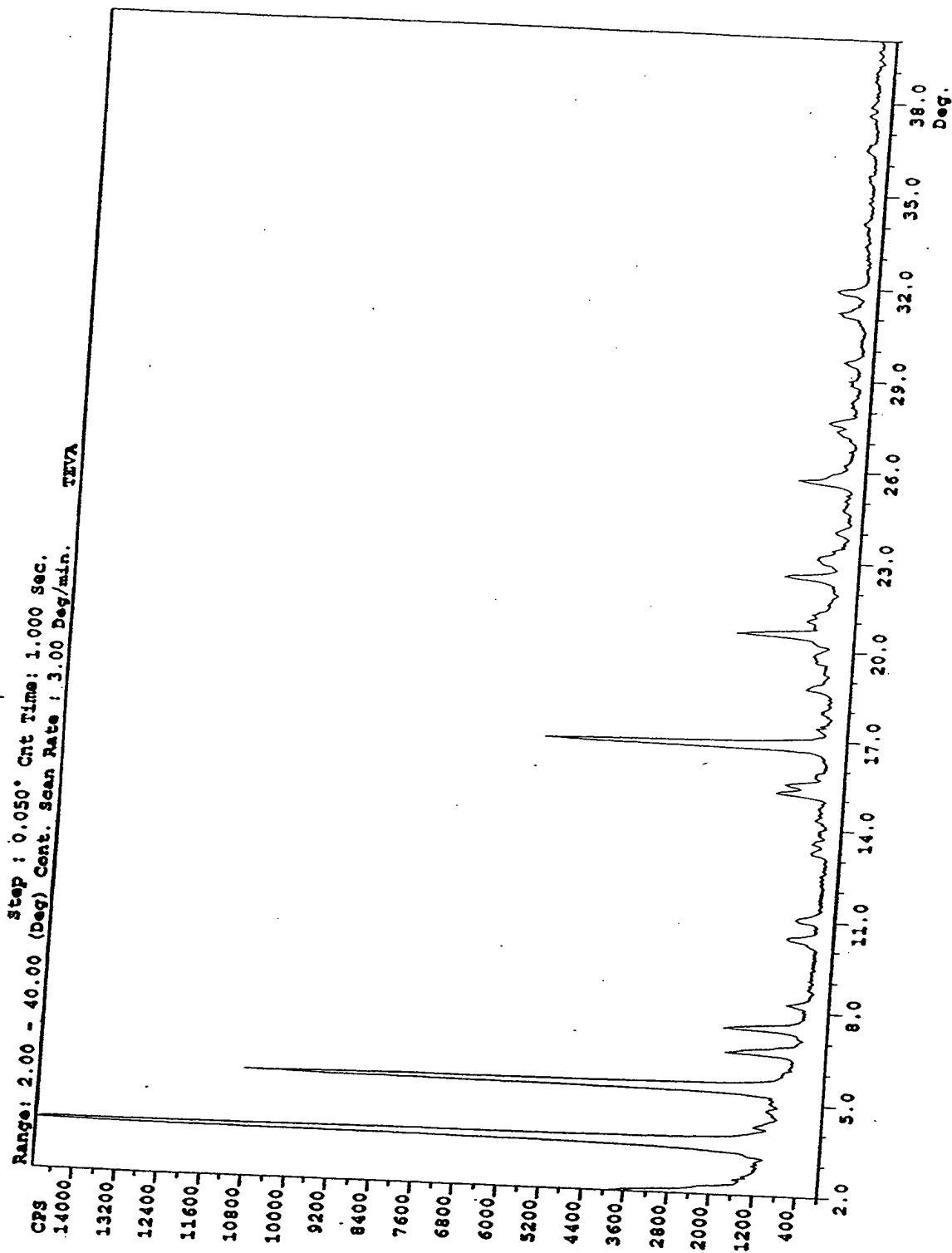




Fig. 8

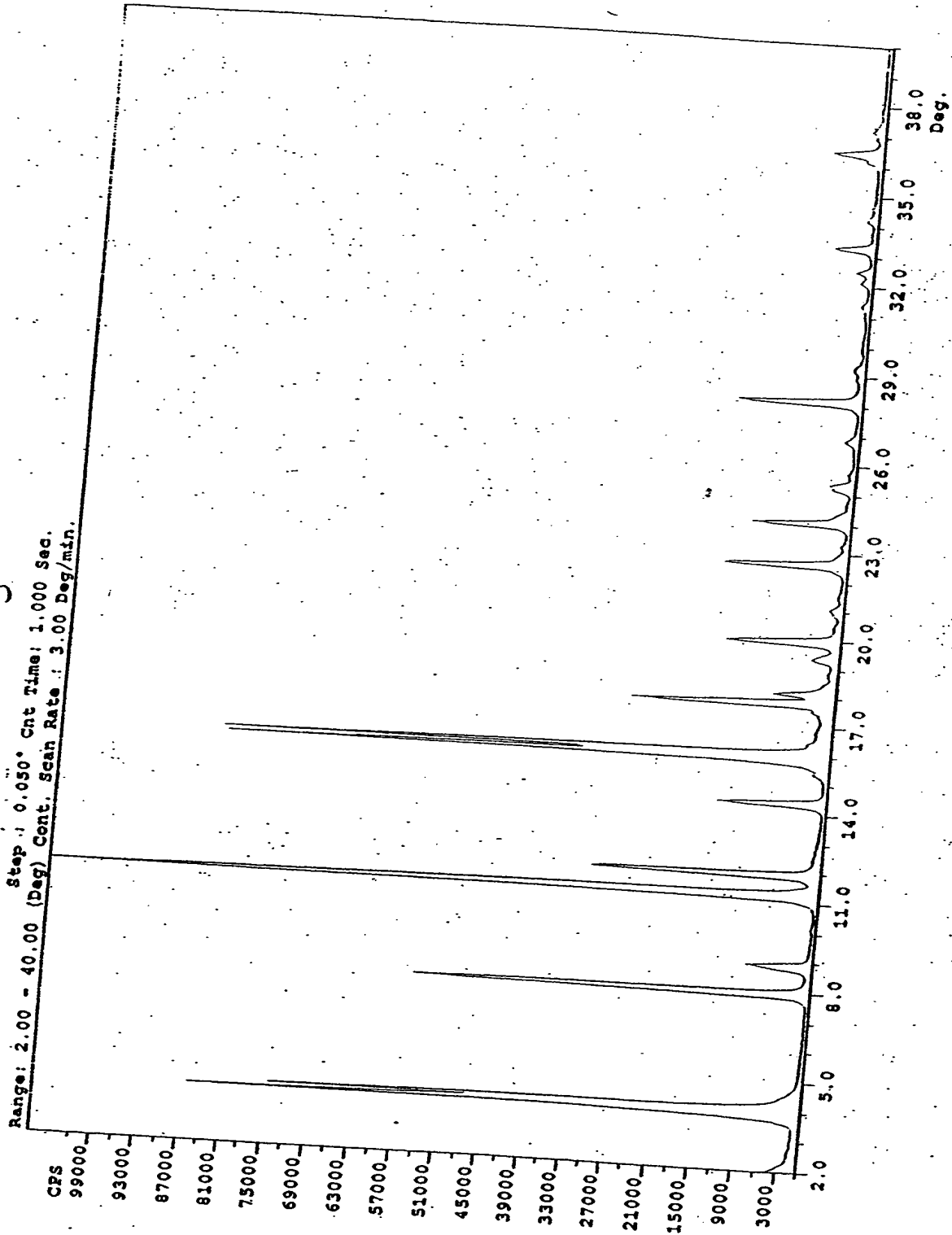


Fig. 9

K

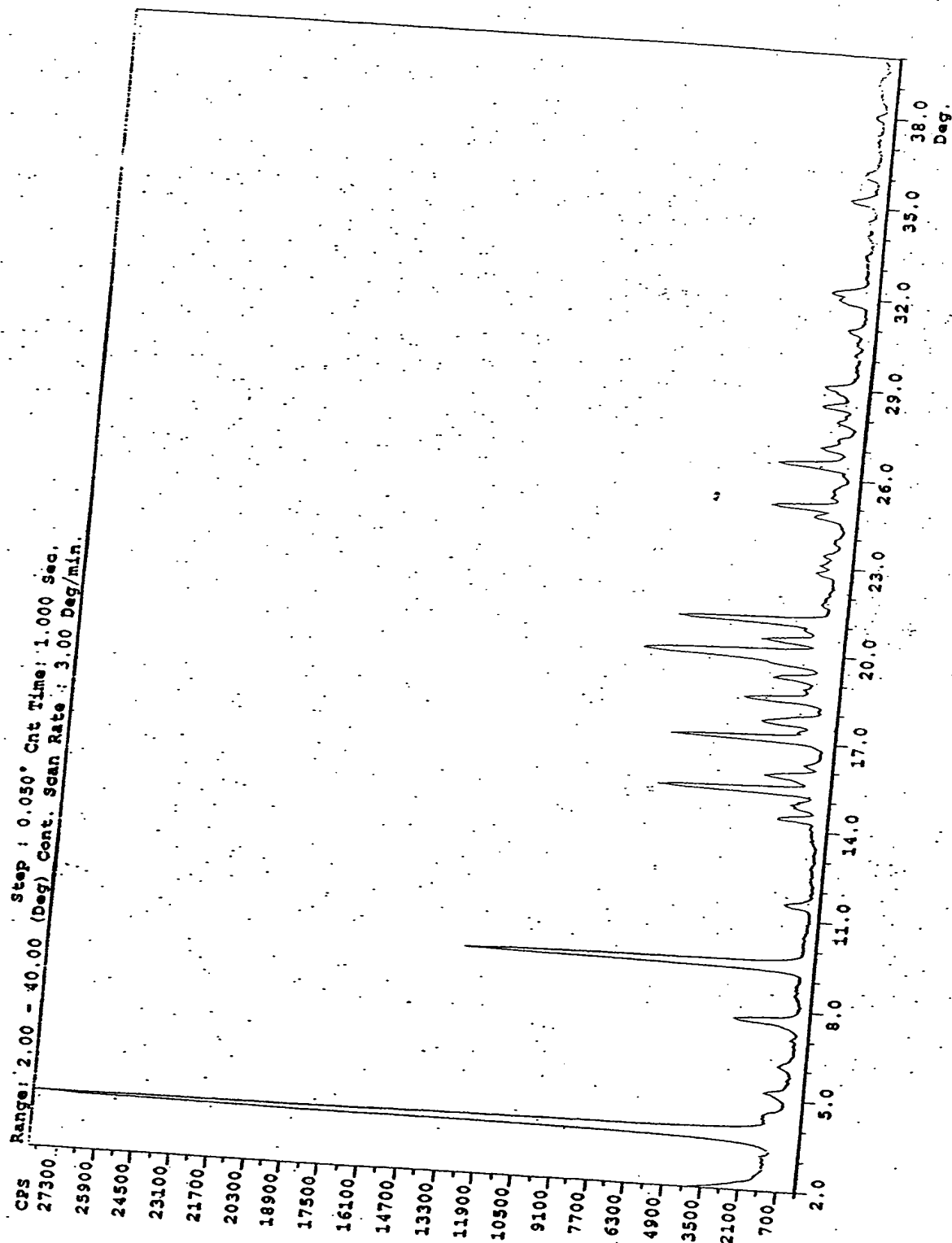


Fig. 10 L

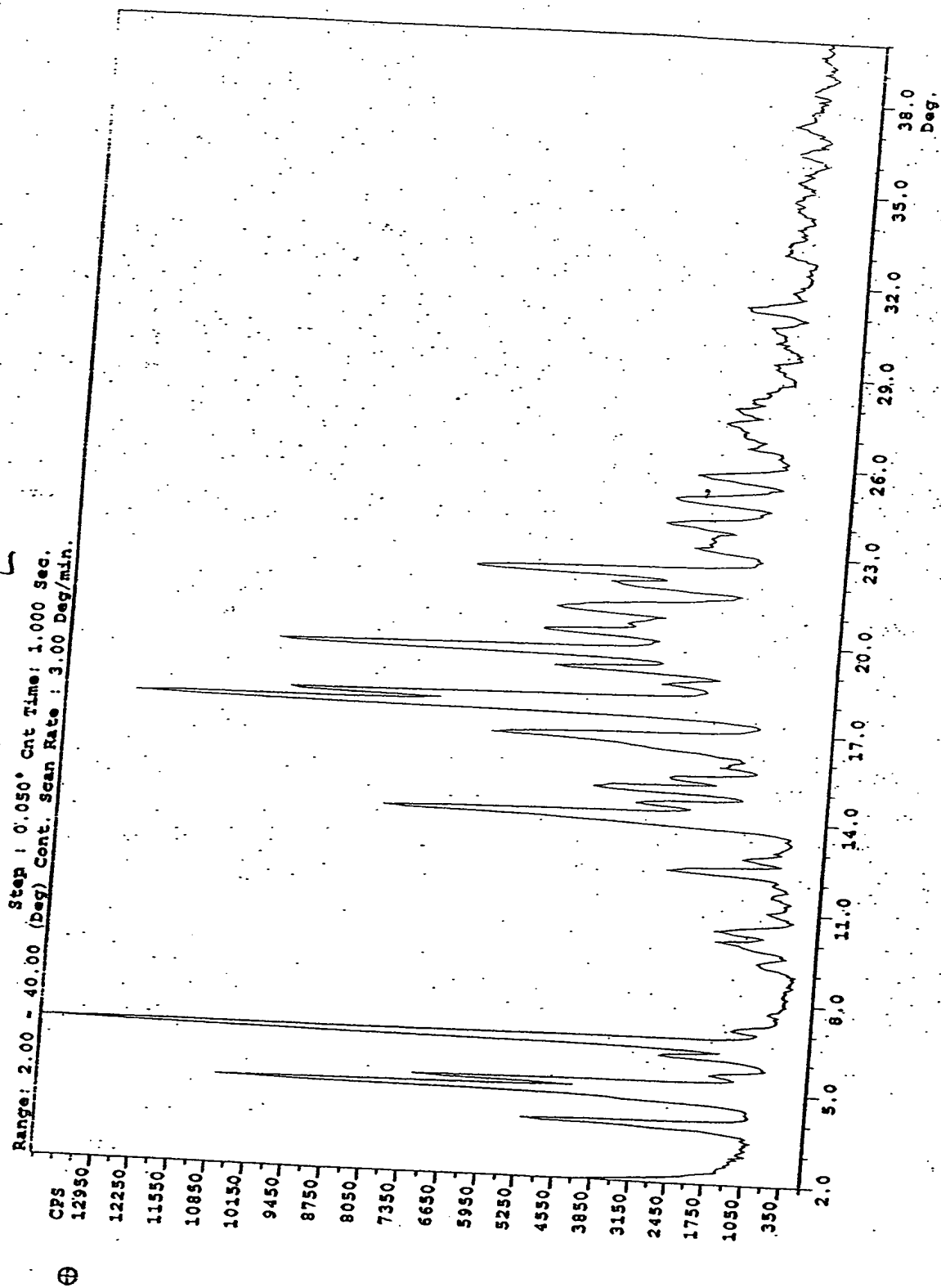
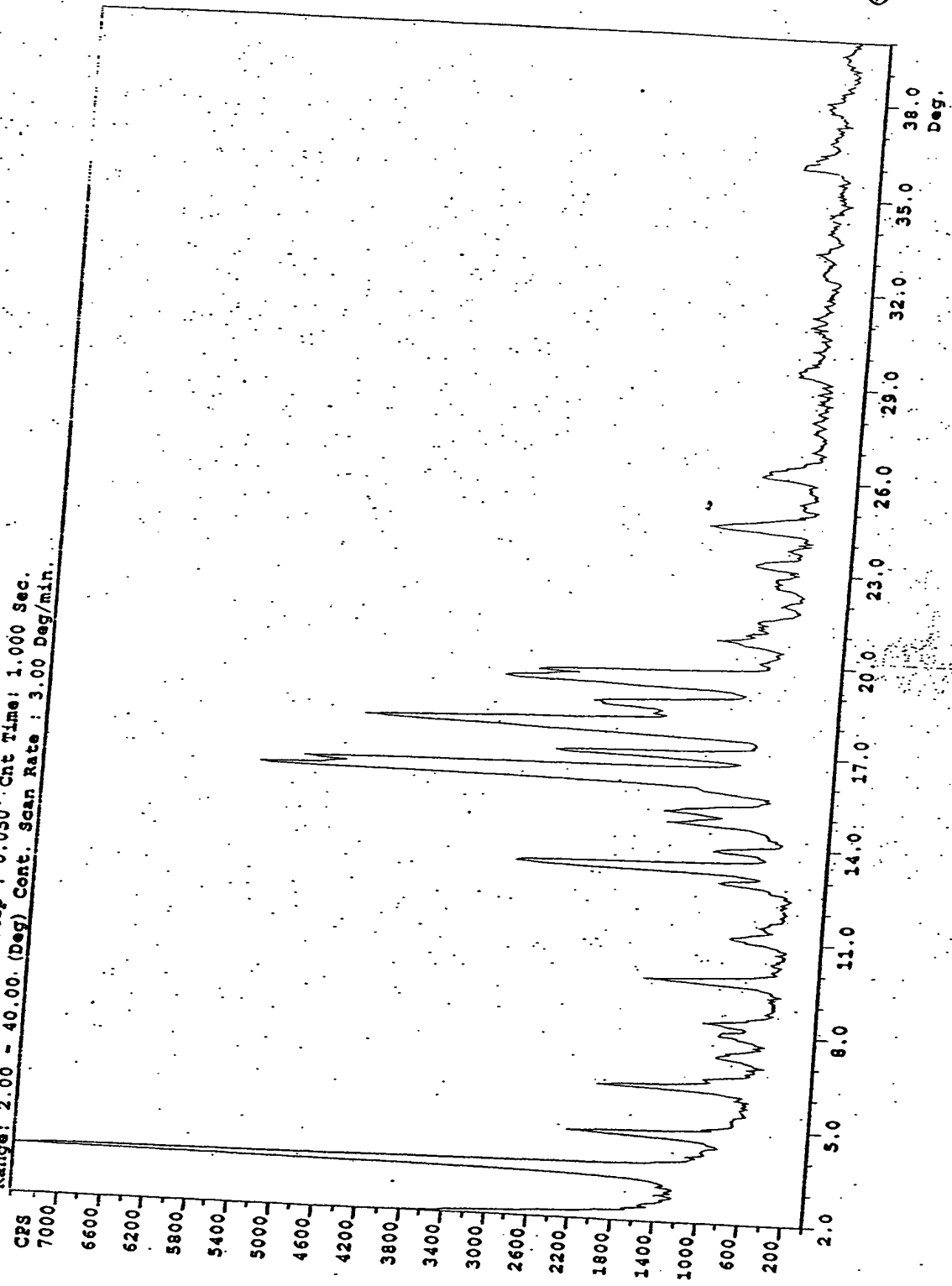


Fig. 11

M

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.  
Step: 0.050 (Deg) Cont. Scan Rate: 3.00 Deg/min.



⊕

Fig. 12

N

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.  
Step: 0.050 (Deg) Cont. Scan Rate: 3.00 Deg/min.

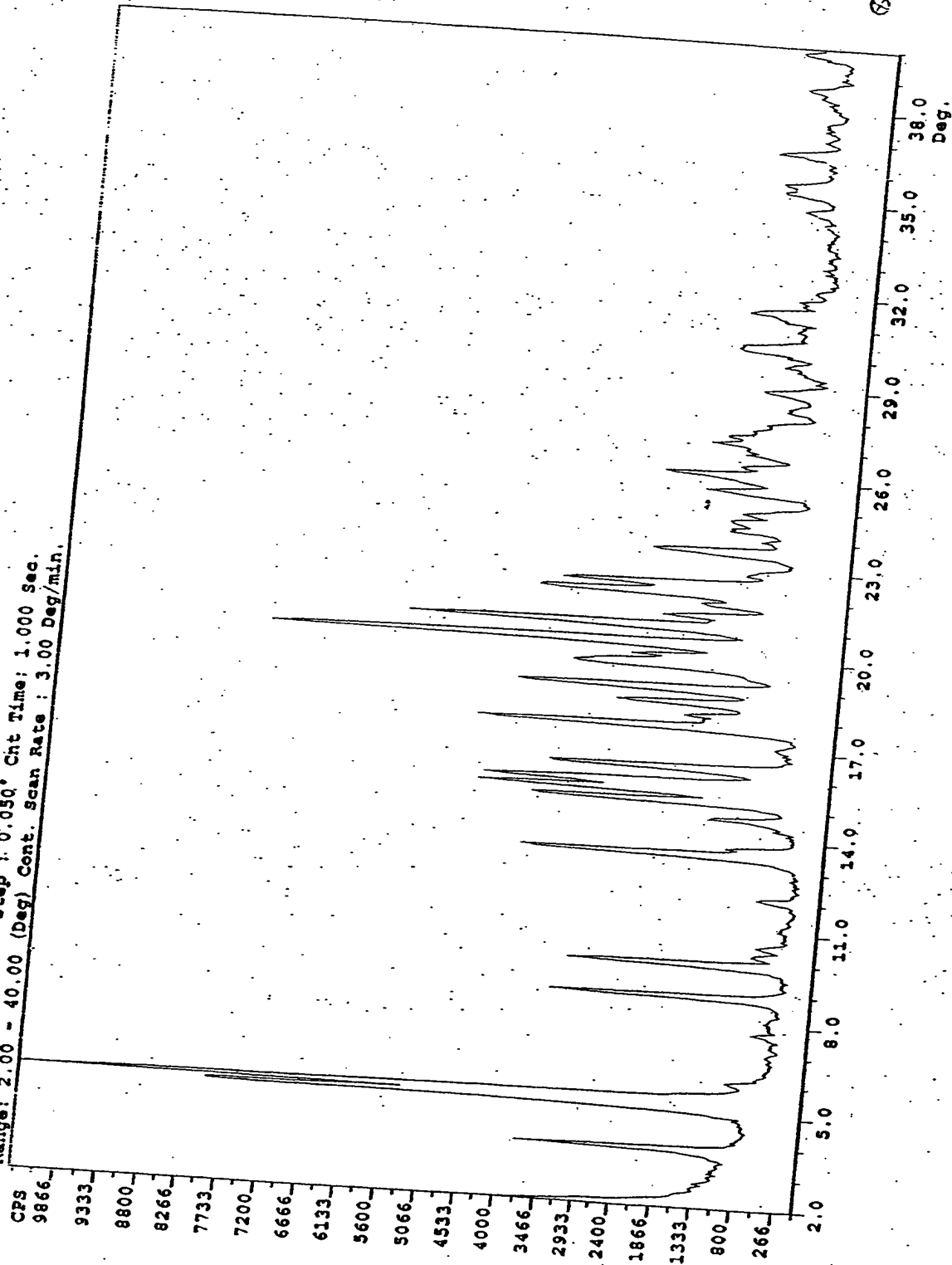


Fig. 13 0

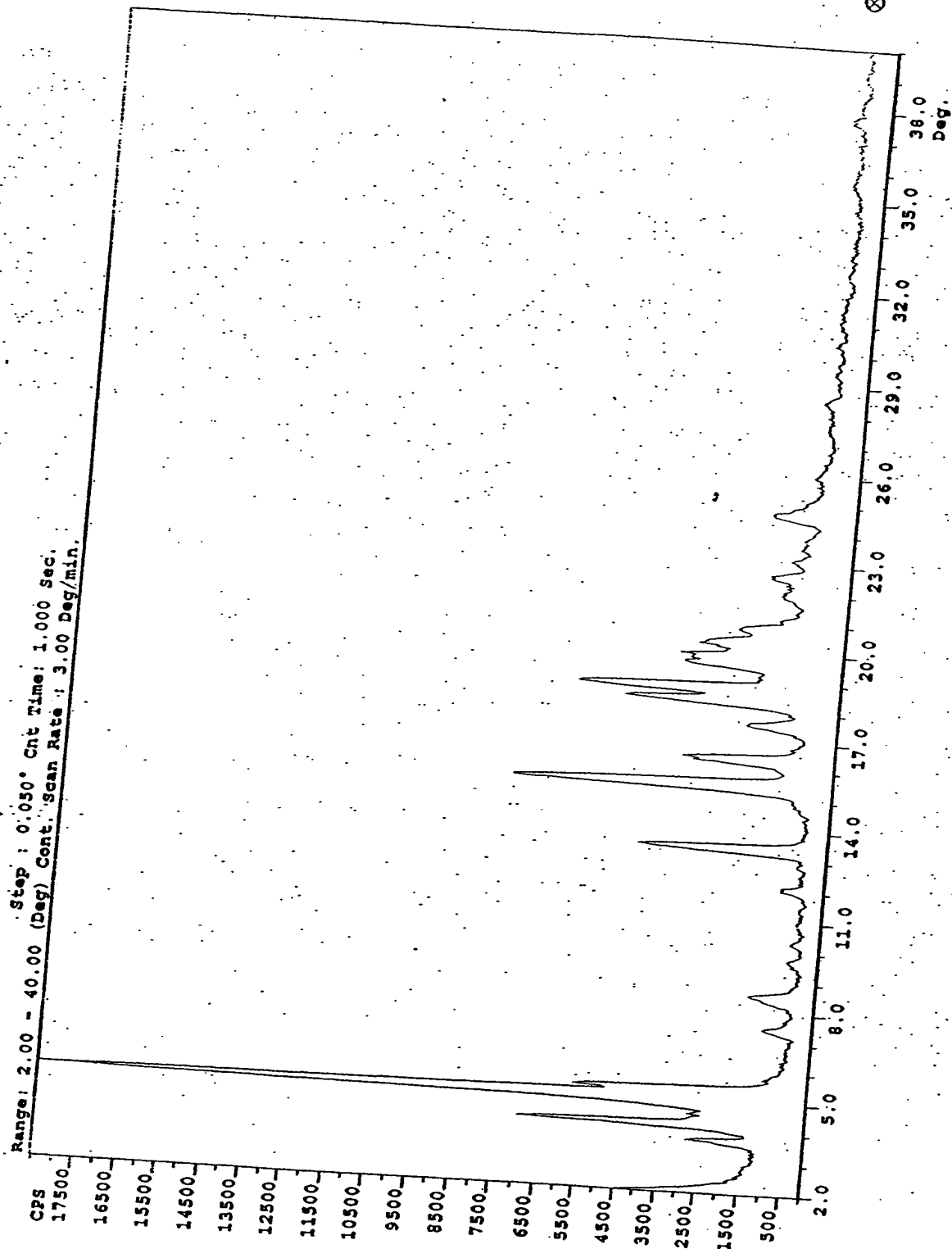


fig. 14

P

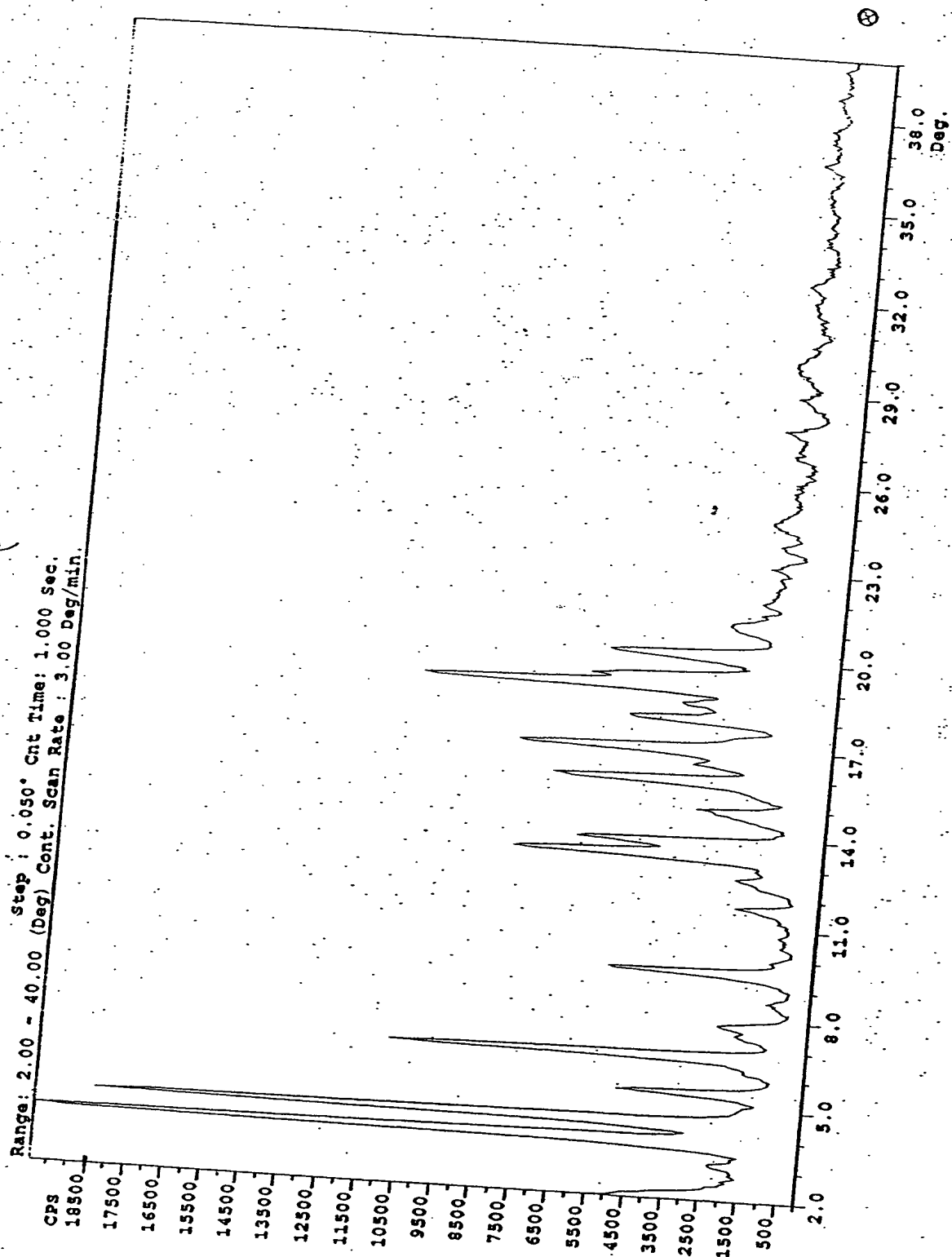


Fig. 15 Q

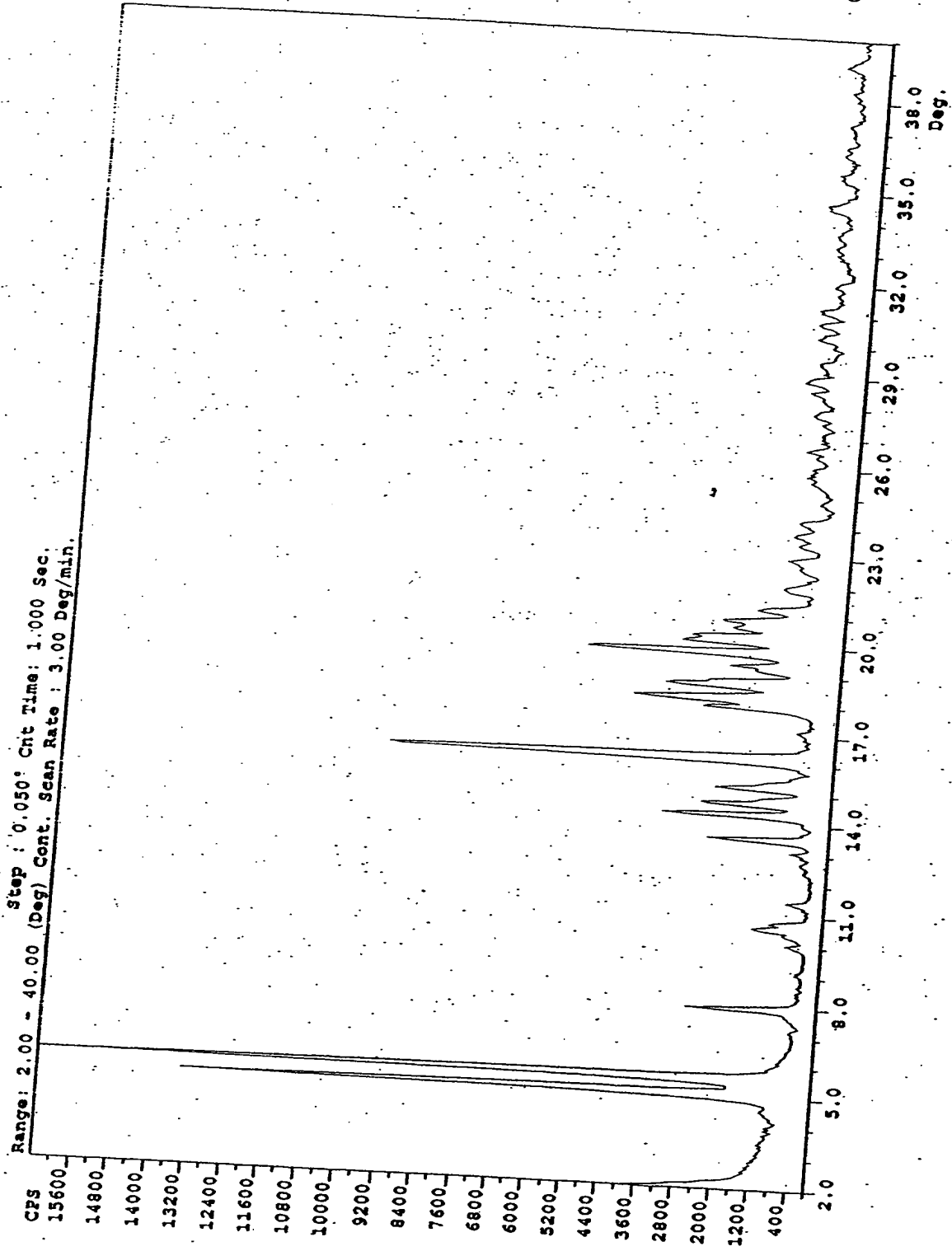




Fig. 16

T

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.  
Scan Rate: 3.00 Deg/min.

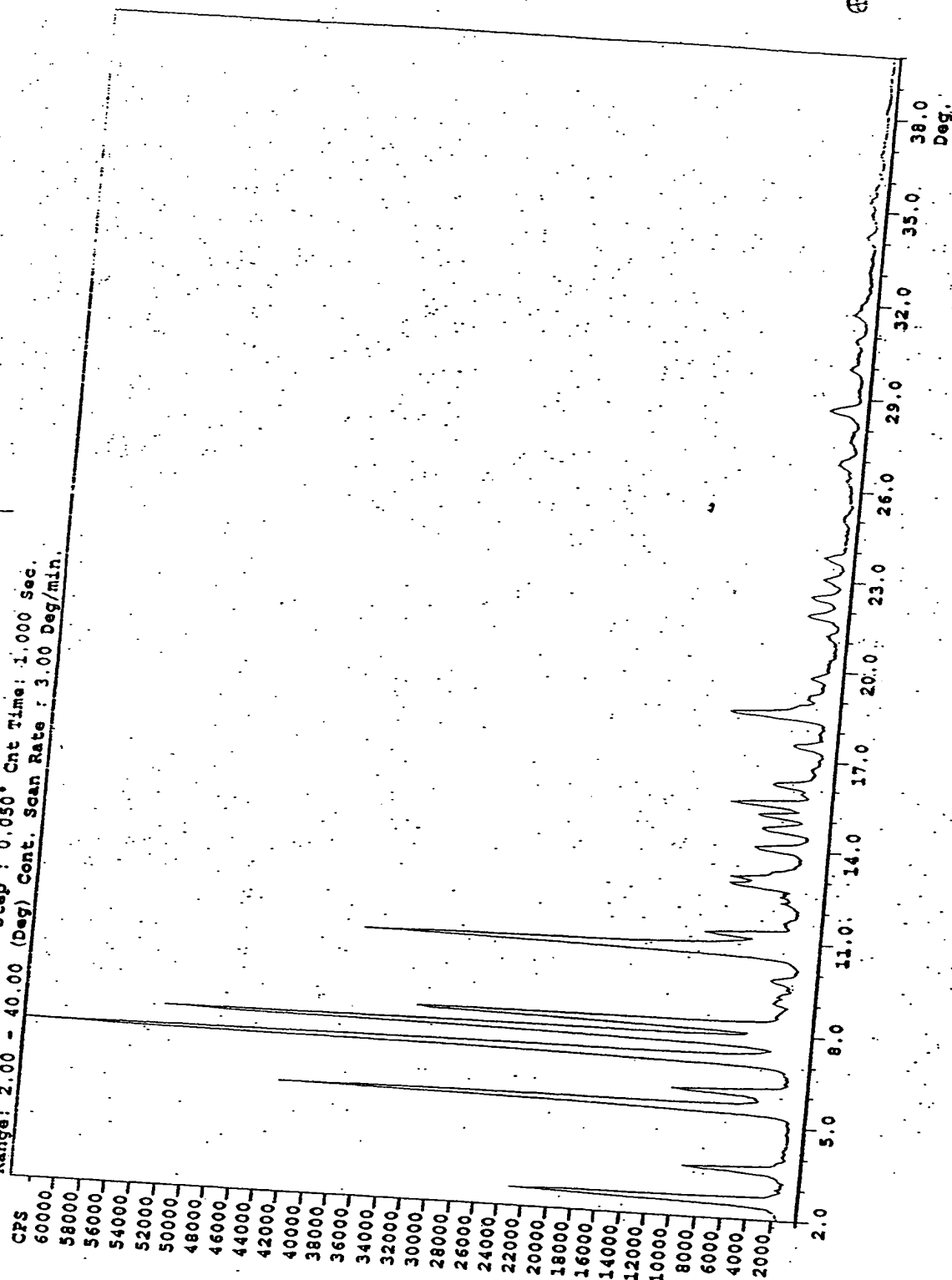


Fig. 17 u

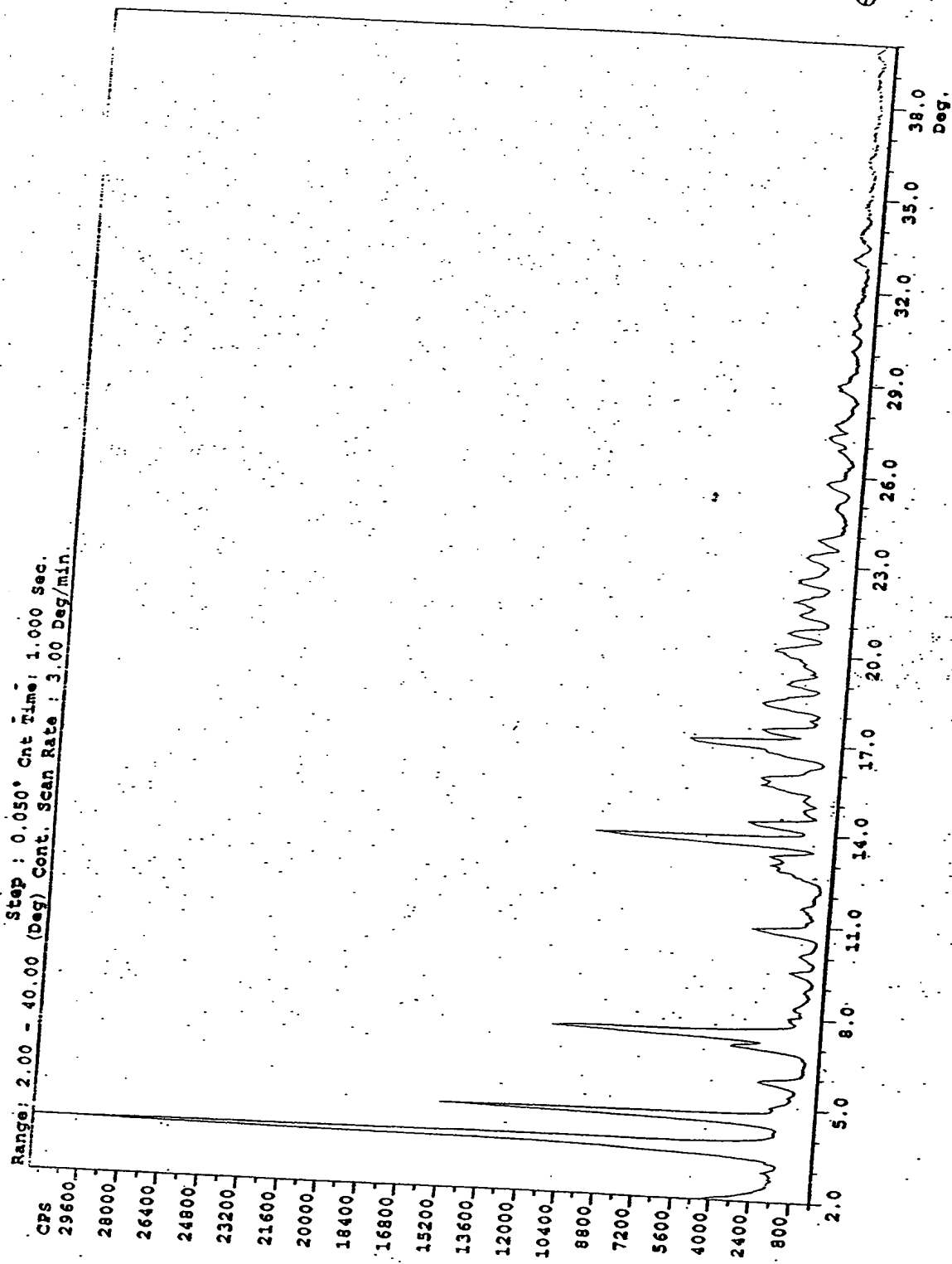


Fig. 18

Range: 2.00 - 40.00 (Deg) Cnt Time: 1.000 Sec.  
Step: 0.050° Cont. Scan Rate: 3.00 Deg/min.

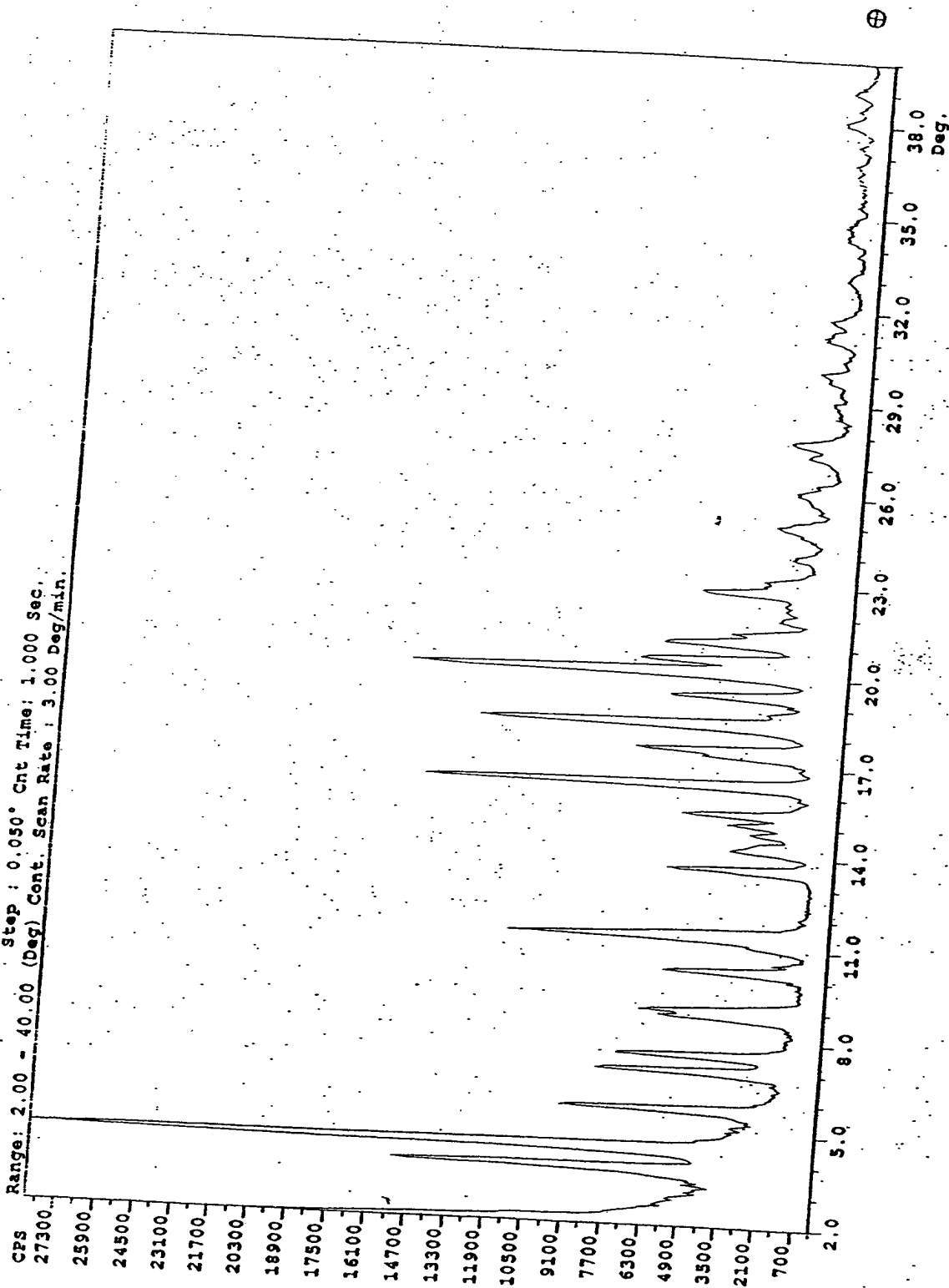


Fig 19  $\gamma$

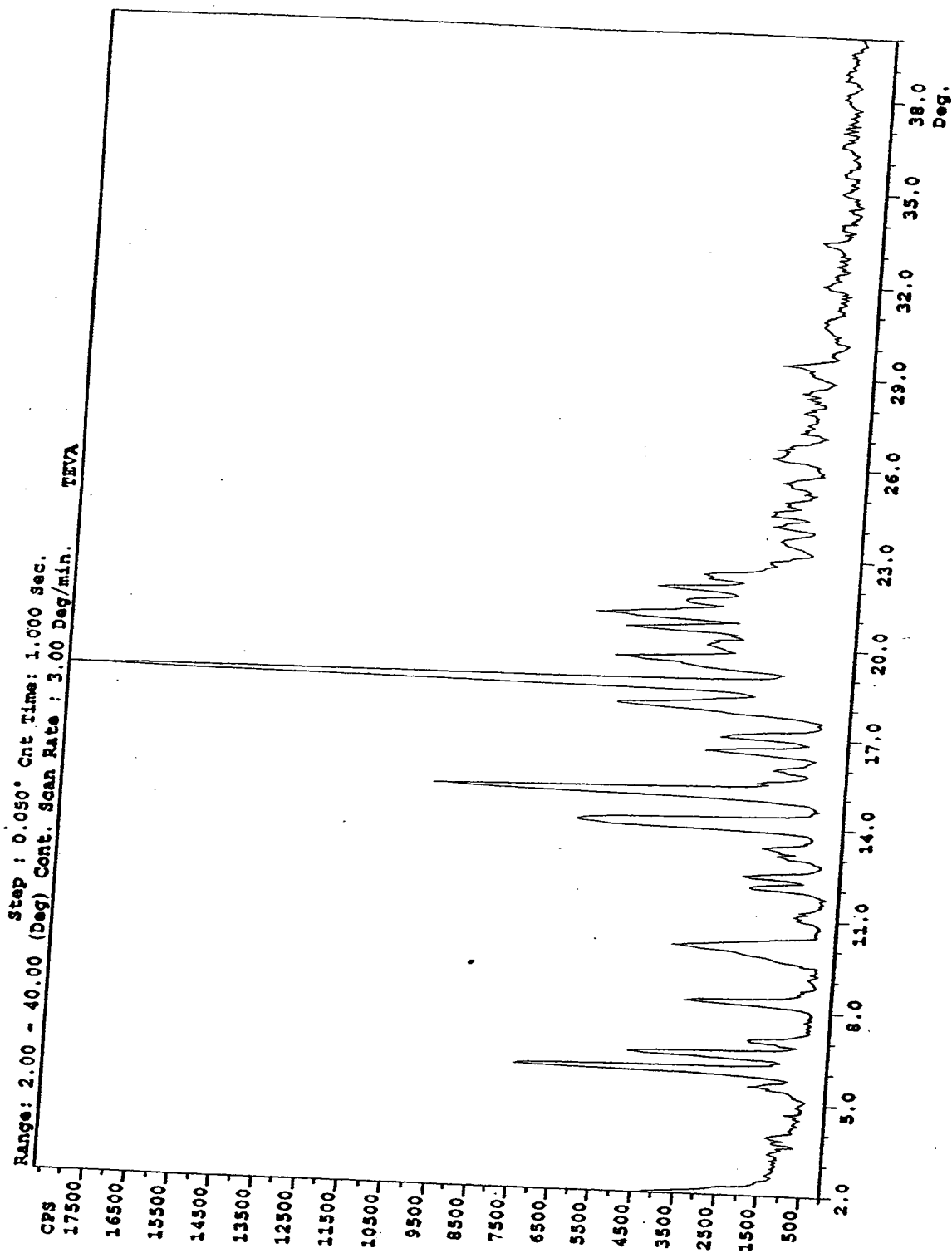


Figure 20 - Nateglinide Form Z

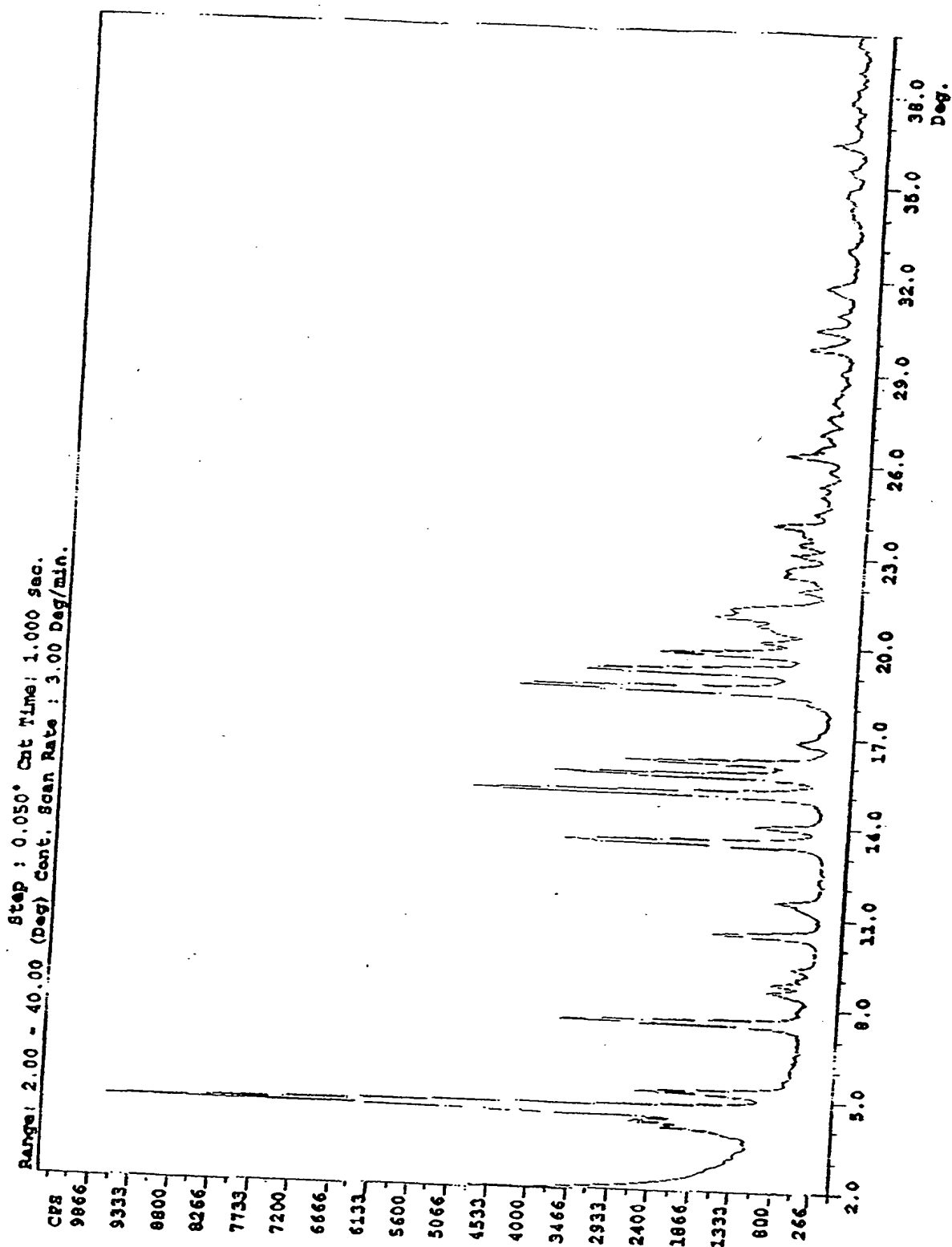


fig 2p x

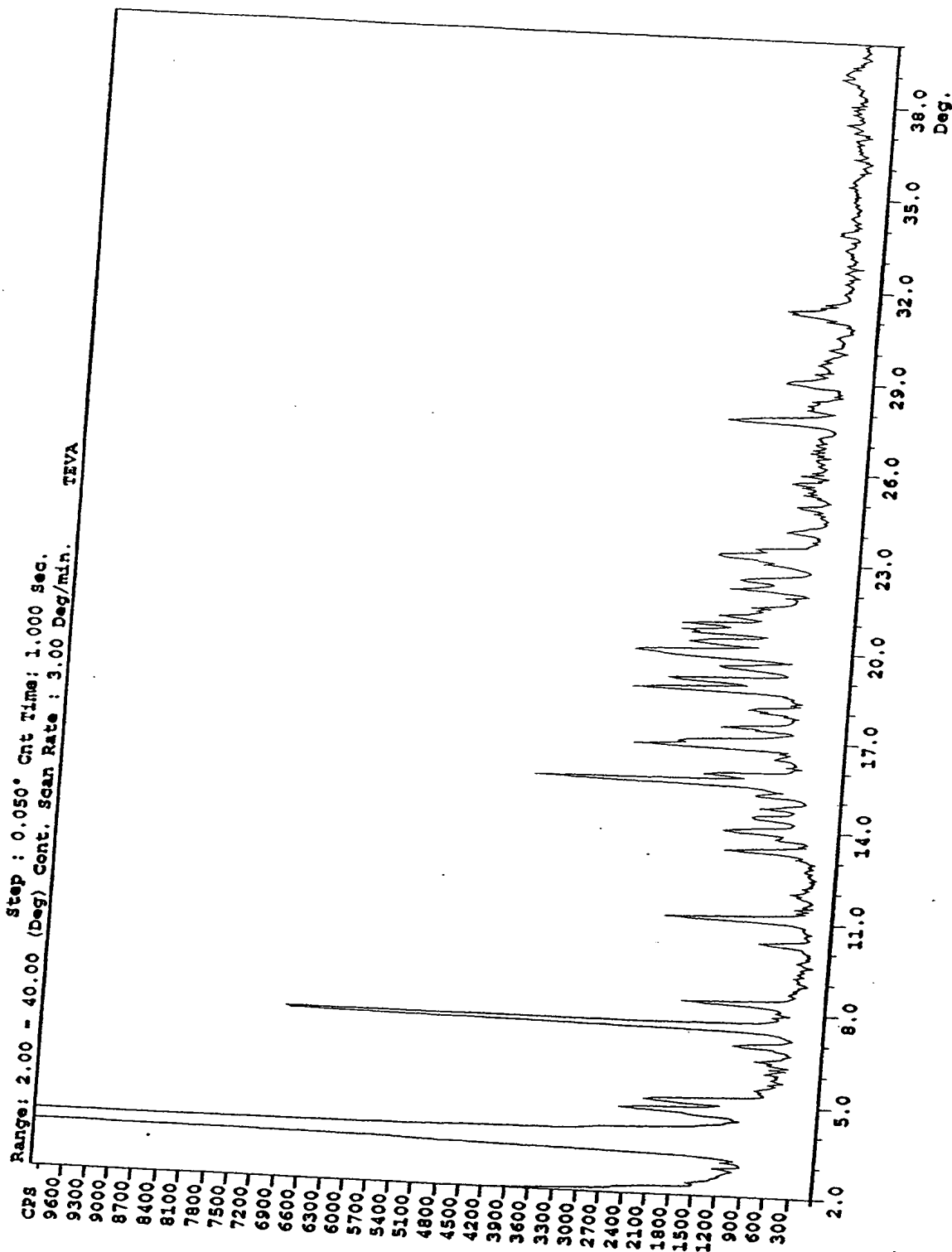


Fig. 2A B

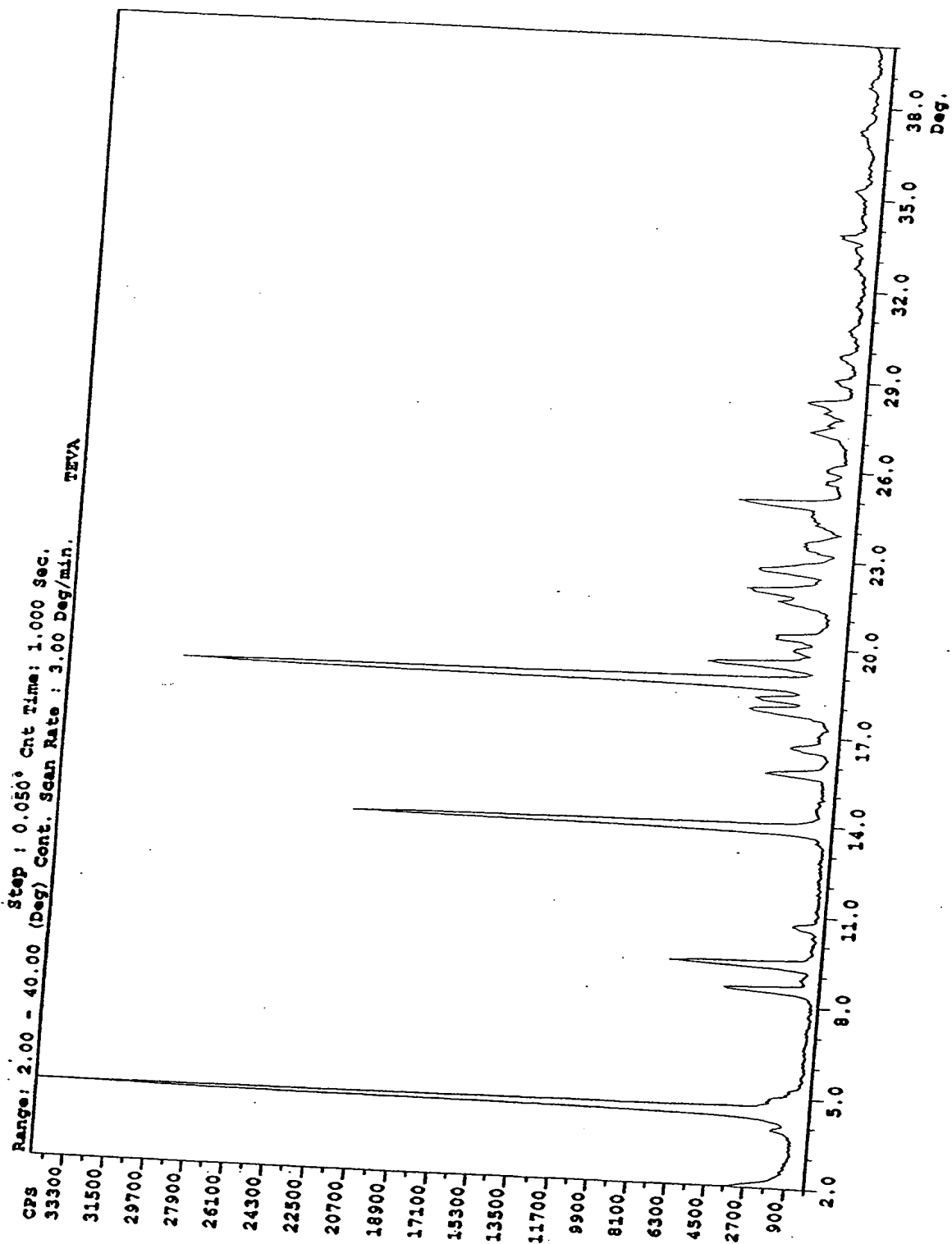


Fig 23 10

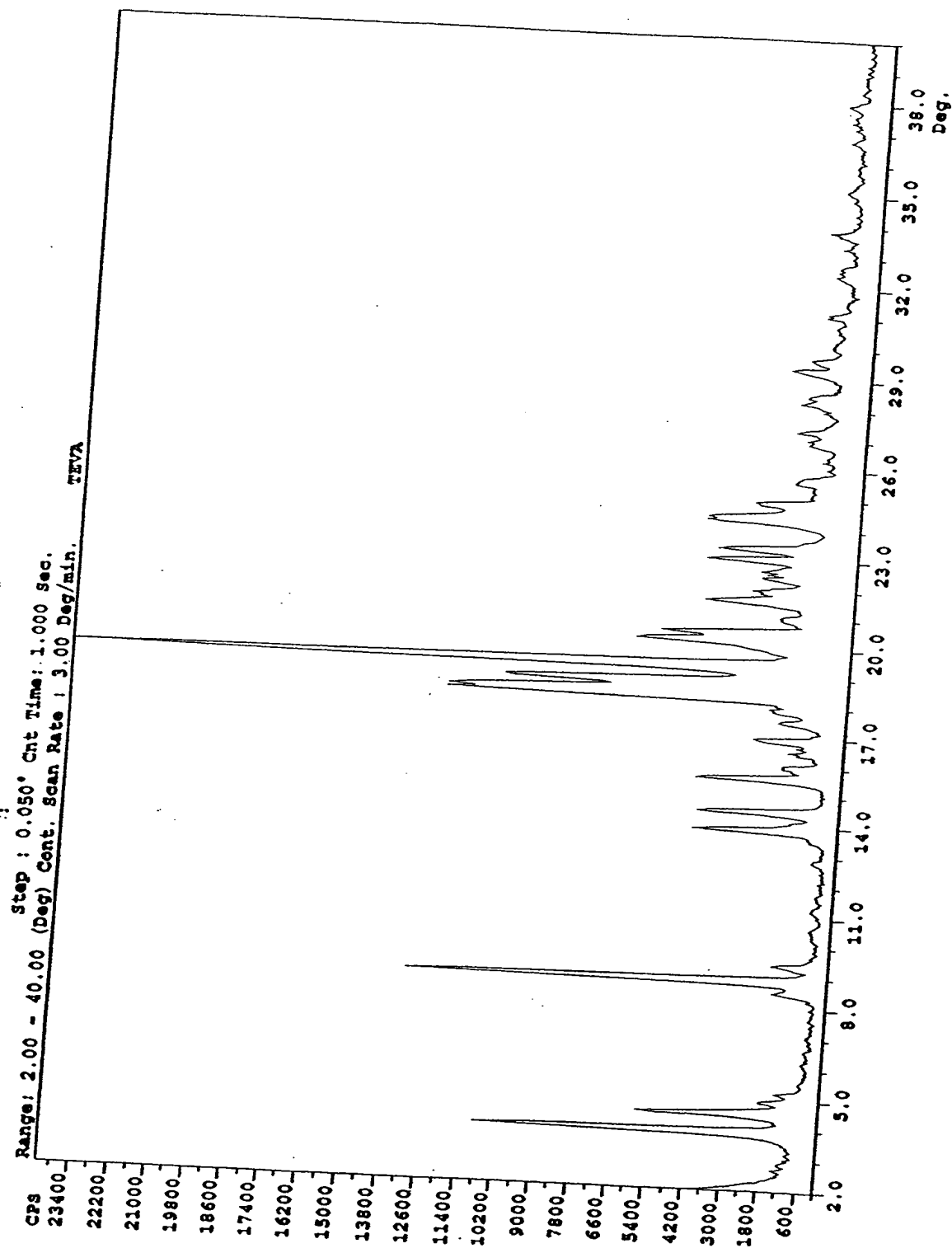




Fig 24

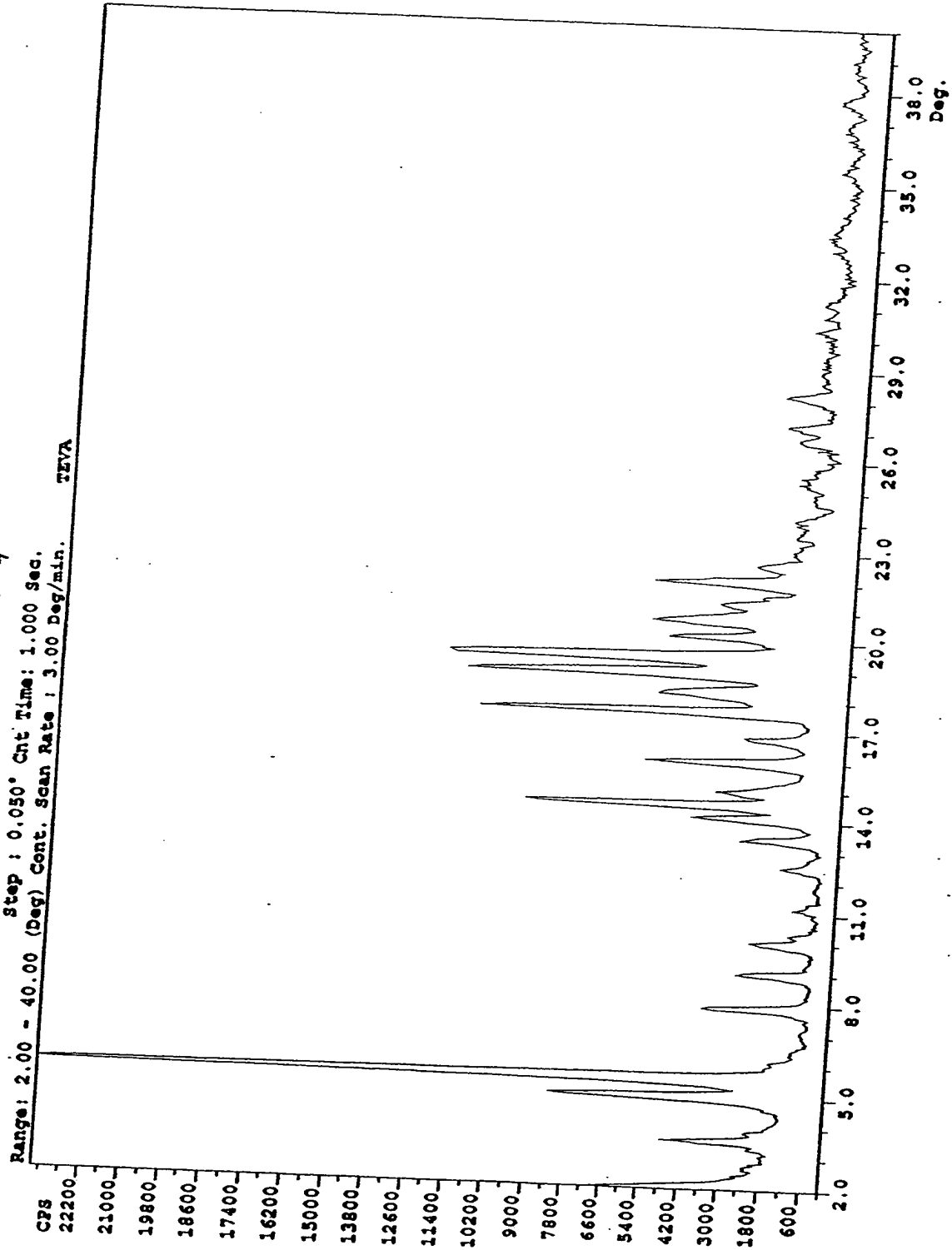


Fig 25

E

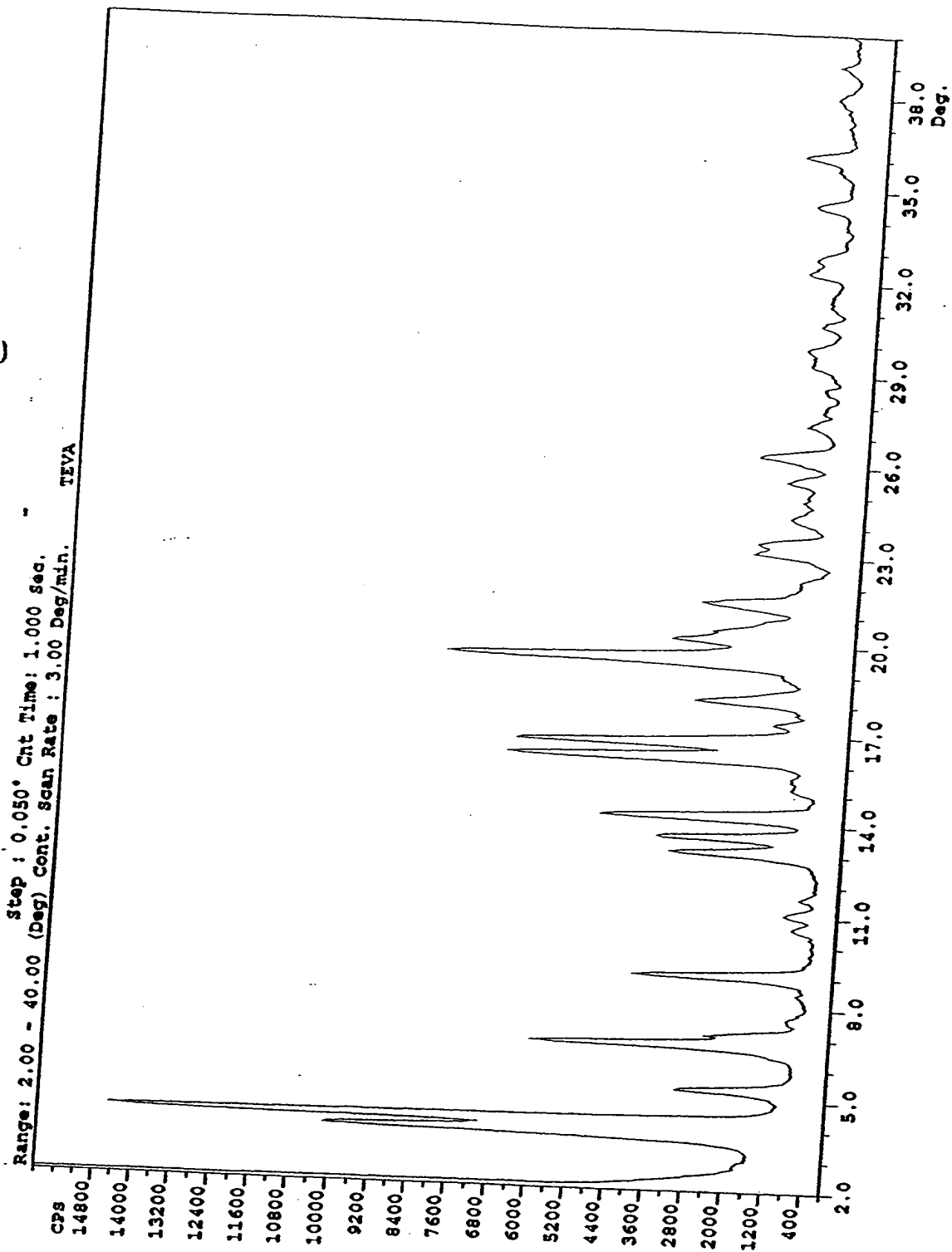
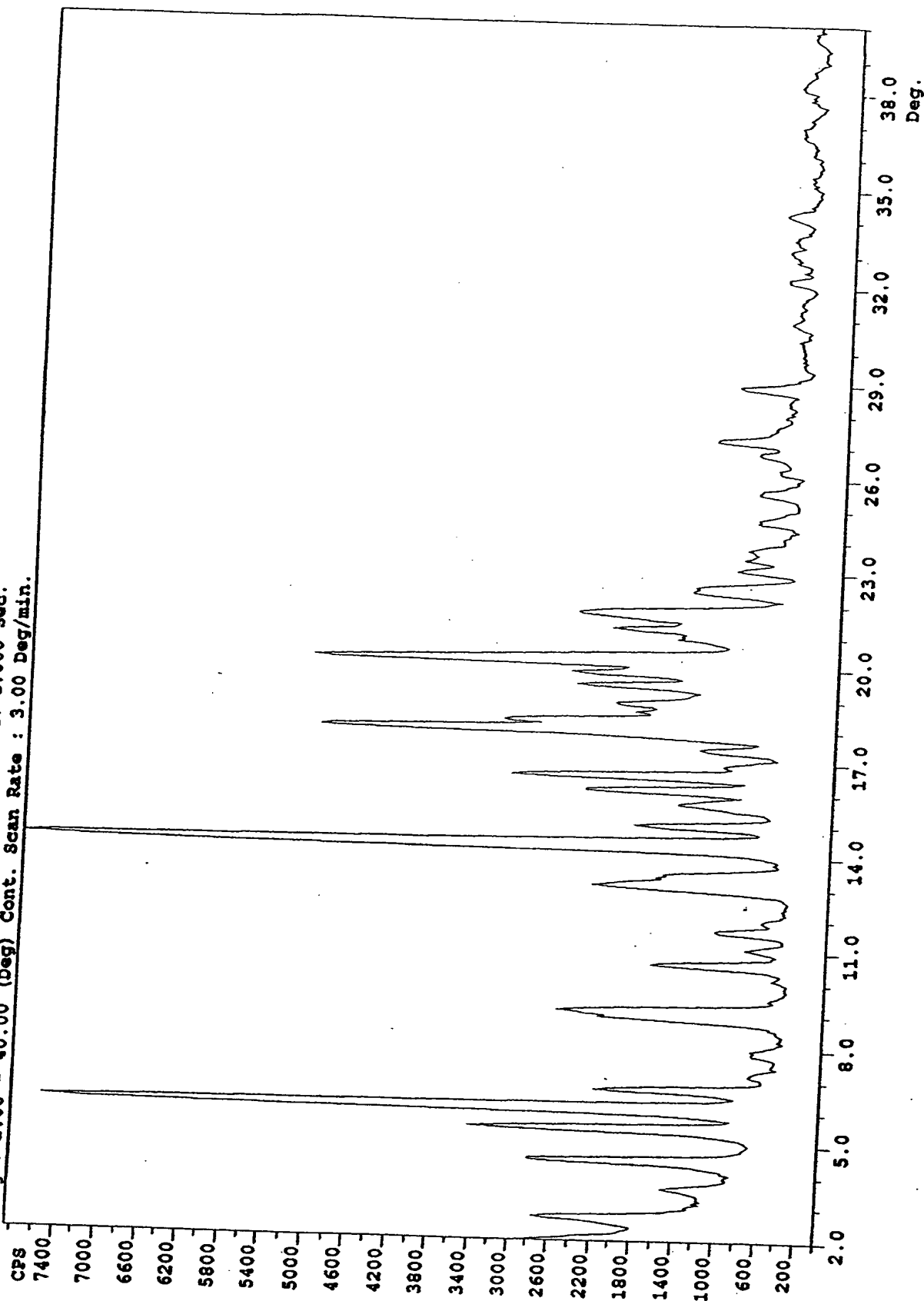


FIGURE 26

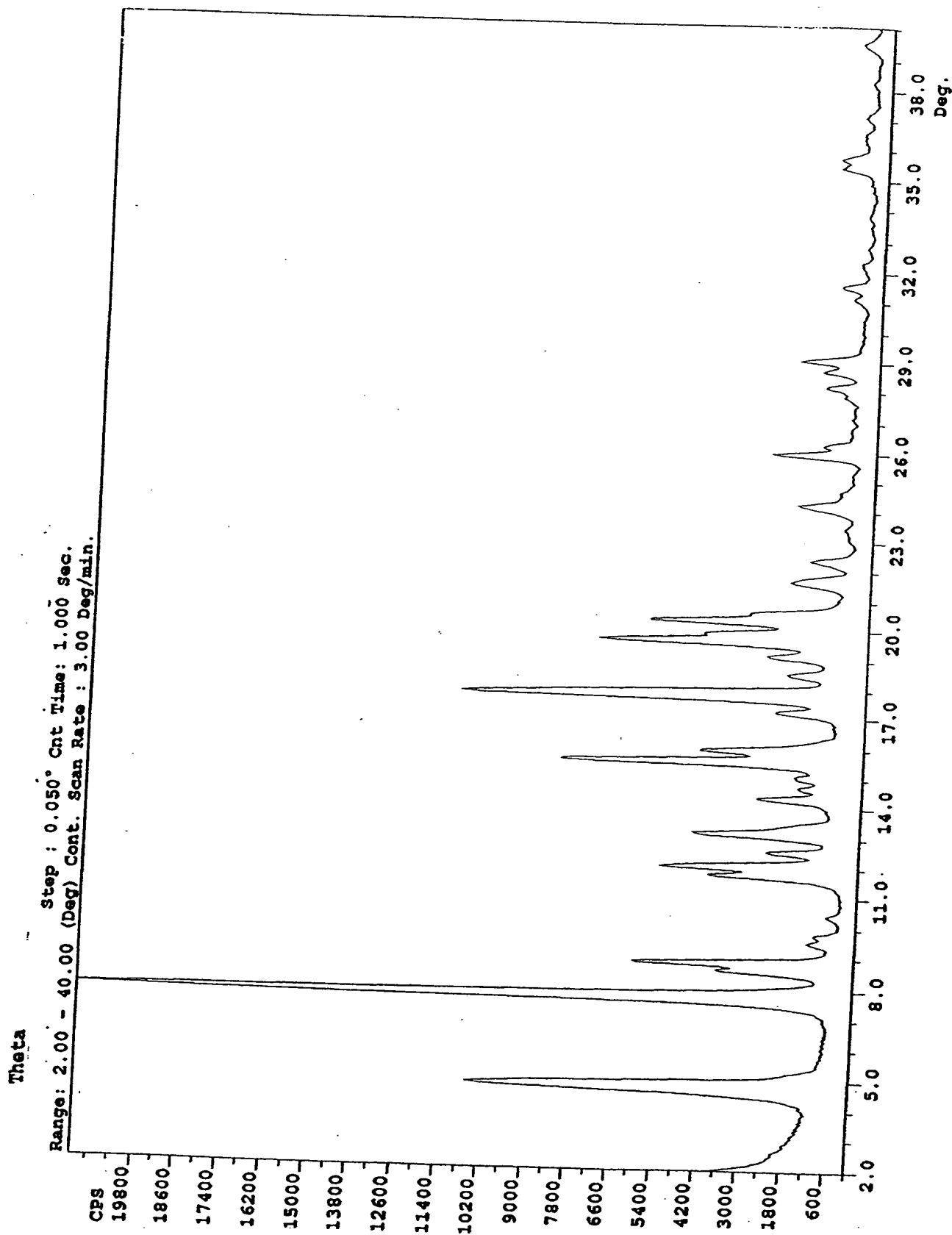
Sigma

Range: 2.00 - 40.00 (Deg) Cont. Scan Rate: 3.00 Deg/min.



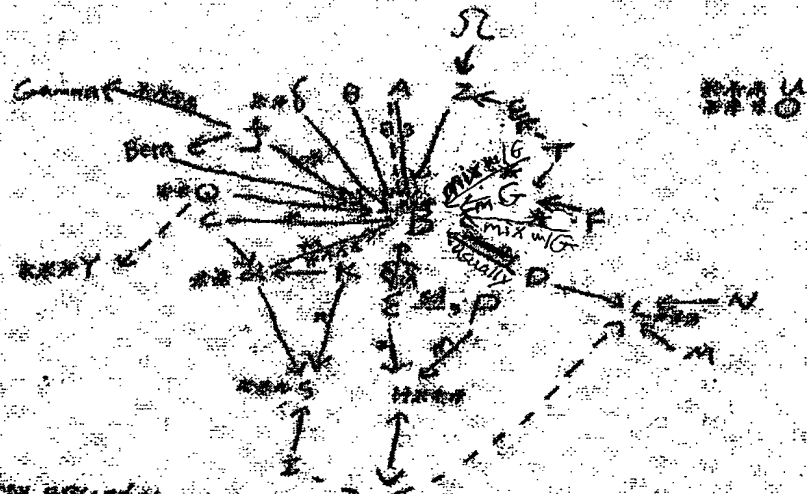
Form (5)

FIGURE 23



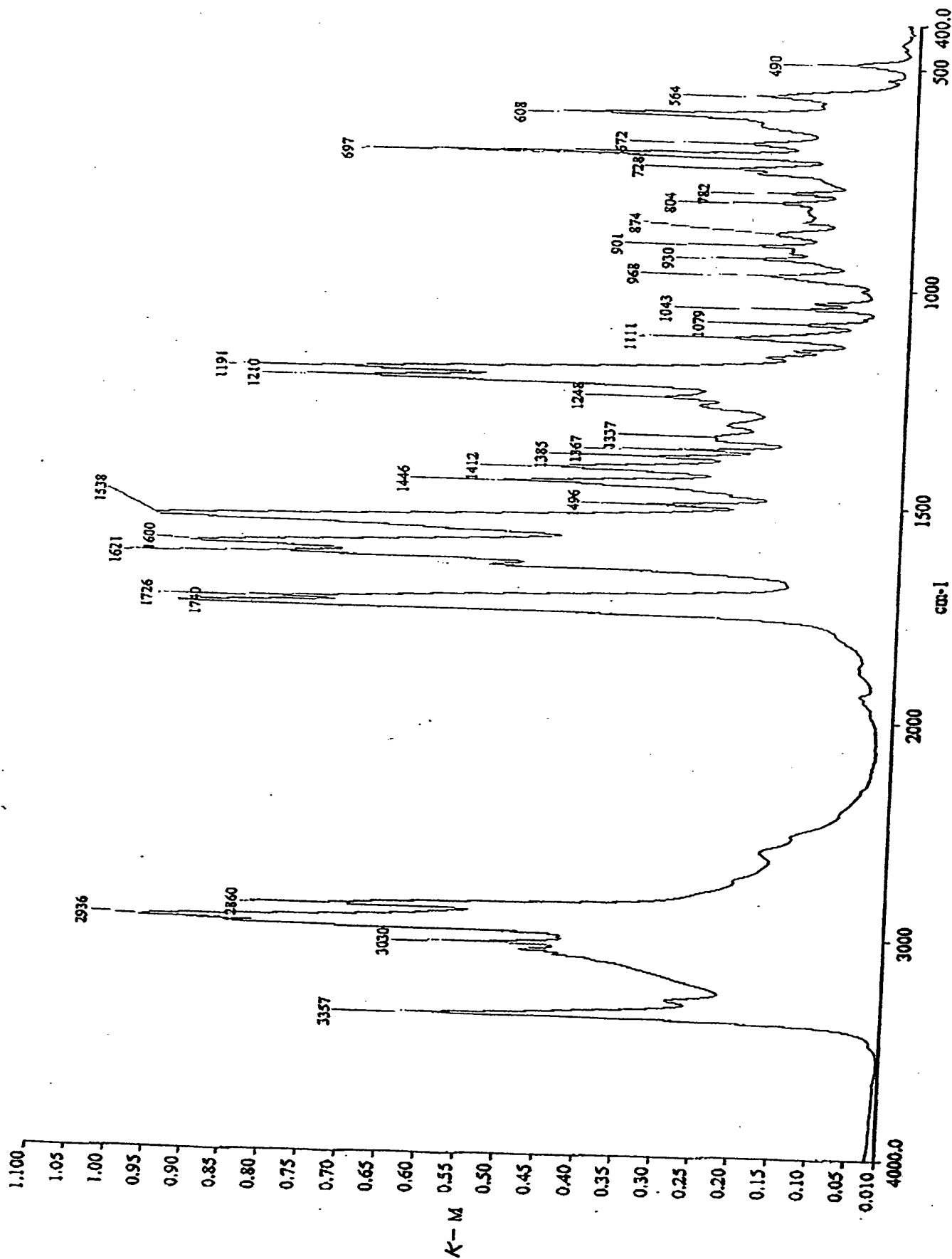
Form 2

Figure 28 - Thermal stability chart



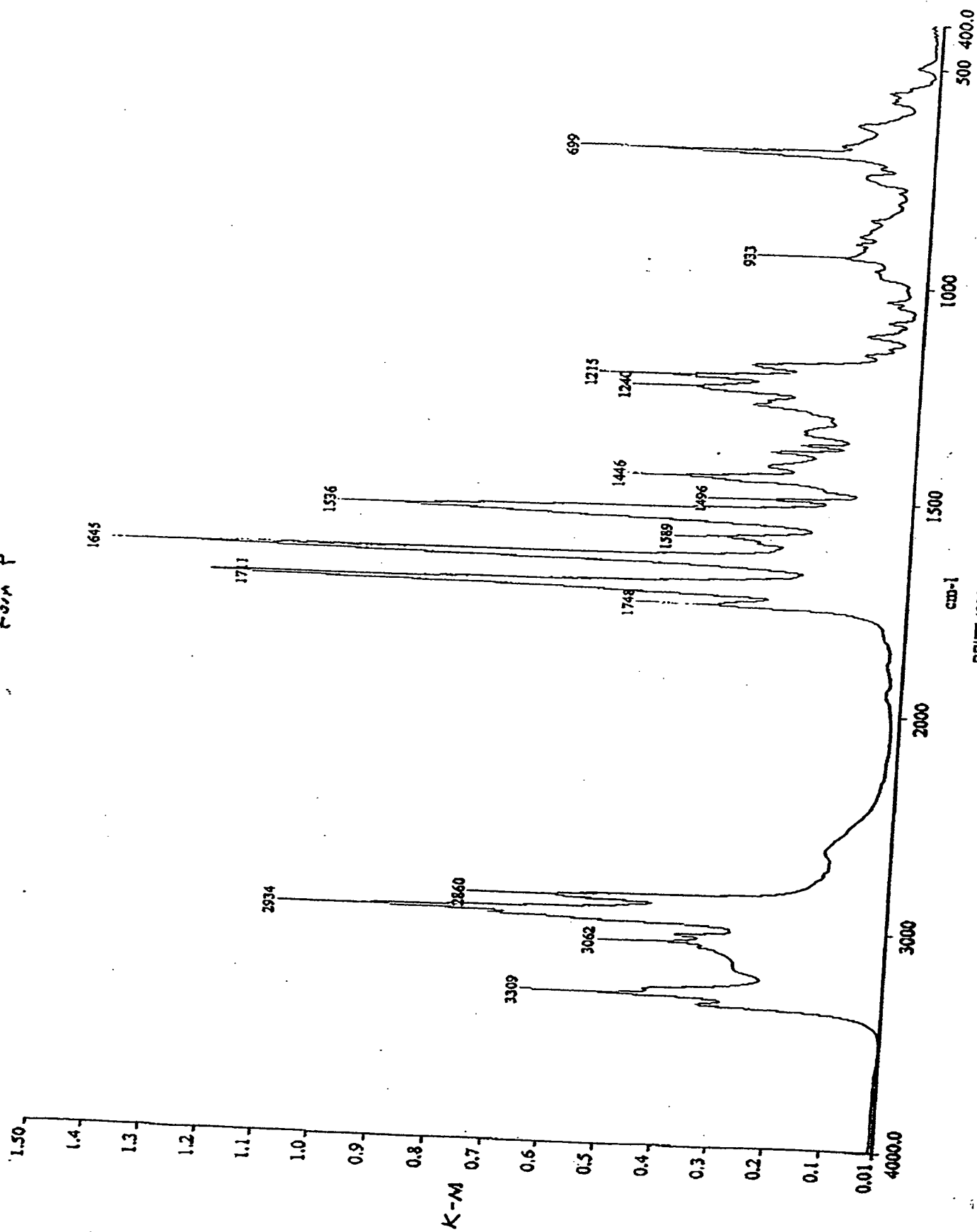
- \* Transformation may proceed through another form
- α Thermally stable at lower maturing temperatures (or 50°C)
- β Thermally stable forms
- > Transformation after storage at room temperature
- in mixture with starting form.
- \*\*\* when starting material contains seeds.
- sol Results might vary depending on the solvents of form Epilva used.

FIGURE 29  
Form 2



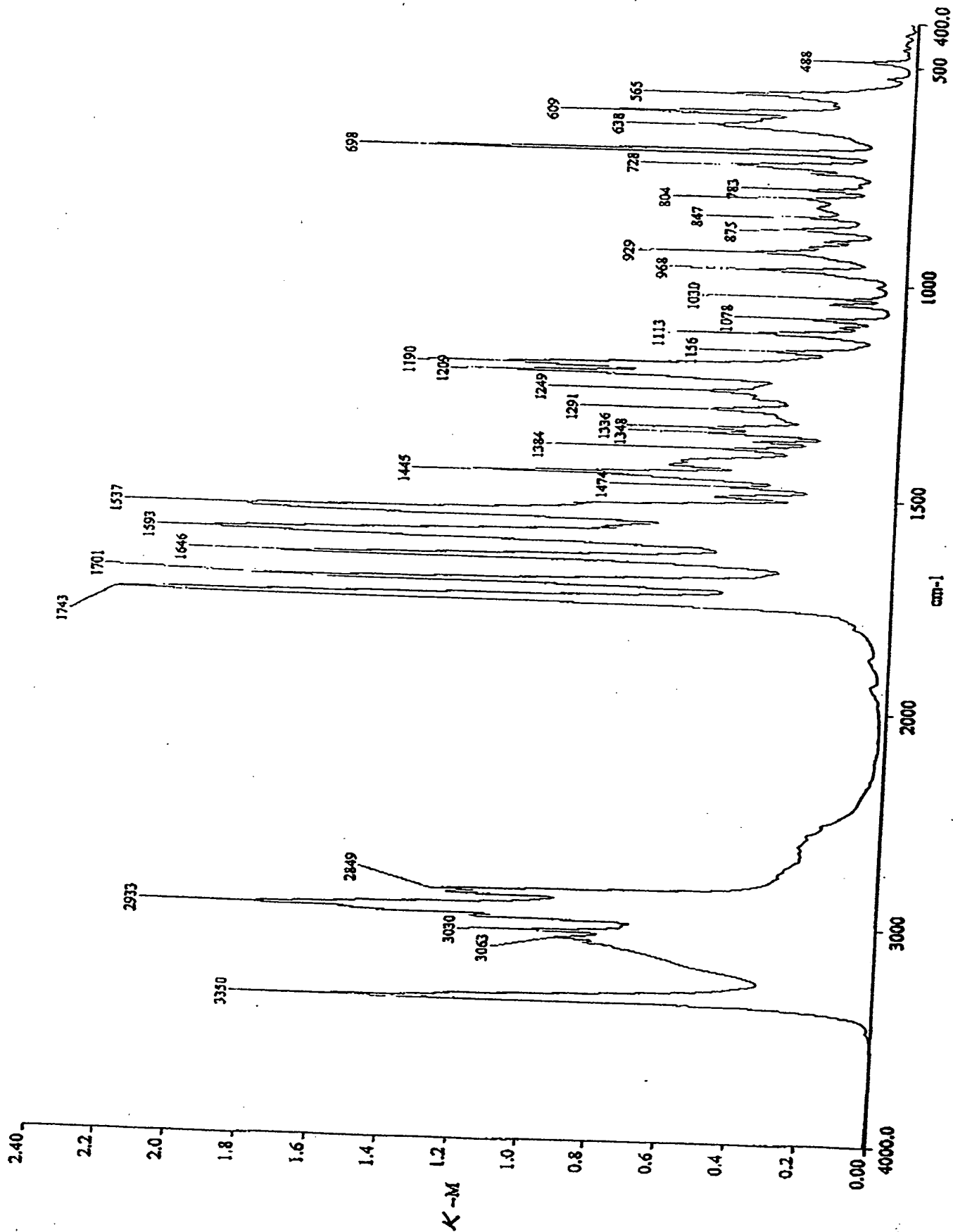
- DRIFT, 4000-400  $\text{cm}^{-1}$ , 16 scans, Resolution: 4.00  $\text{cm}^{-1}$

FIGURE 30  
- Form P



DRIFT, 4000-400 CM-1, 16 scans, Resolution: 4.00cm-1

FIGURE 30  
For U



- DRIFT, 4000-400cm⁻¹, 16 scans, resolution: 4.0cm⁻¹



Figure 32 - Nateglinide Form Z

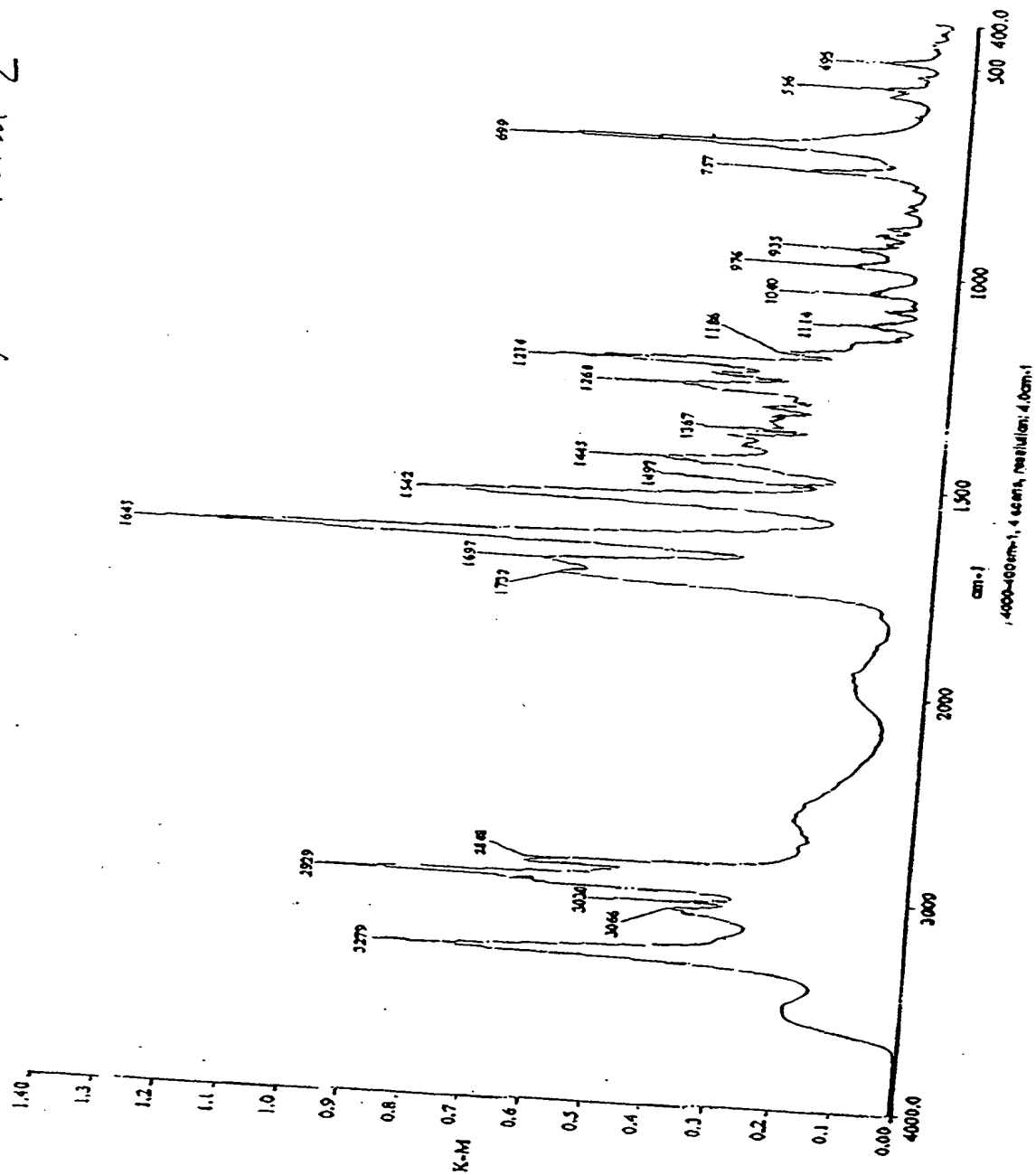


FIGURE 33  
Form α

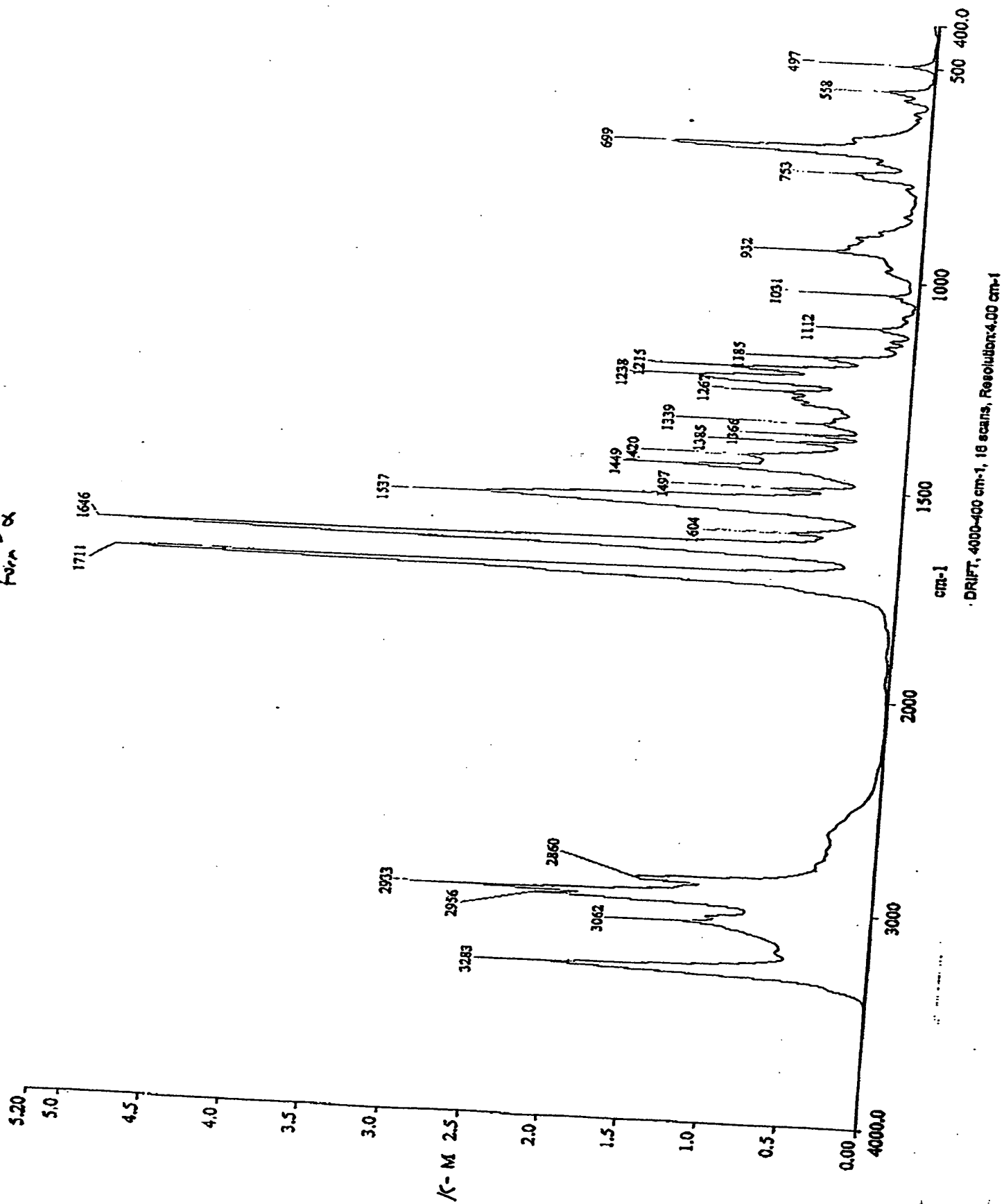
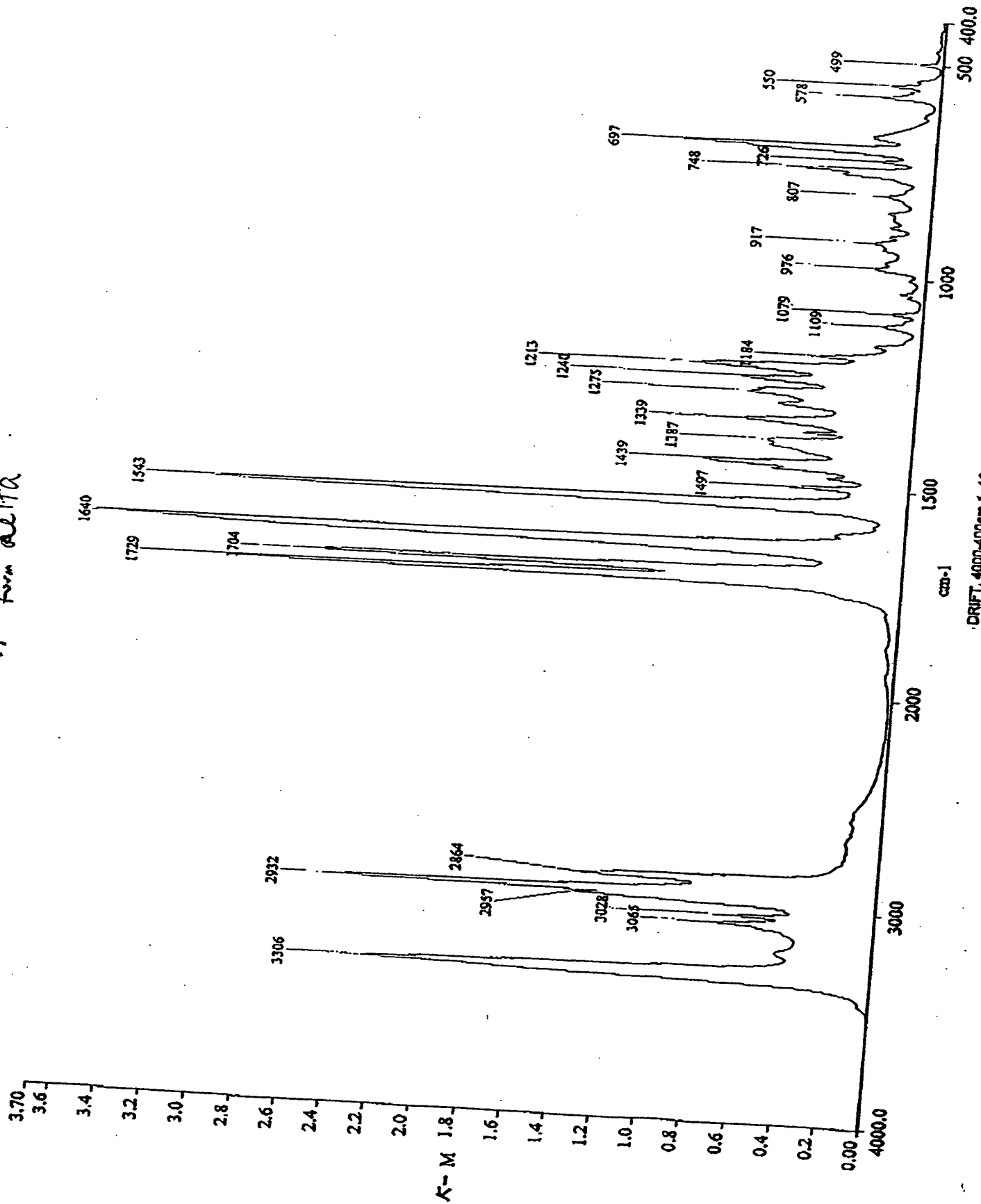
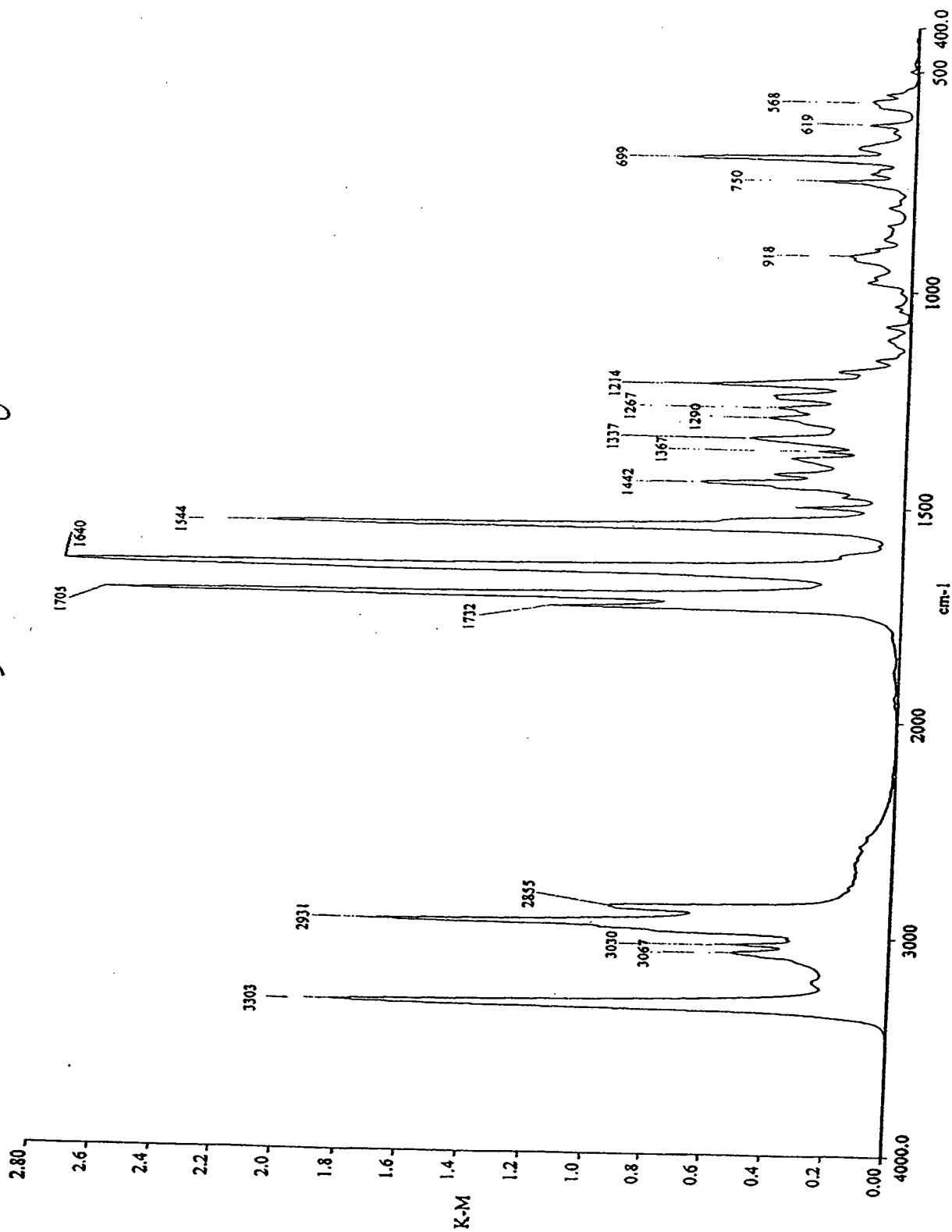


FIGURE 34 Form Delta



DRIFT, 4000-400cm-1, 16 scans, resolution: 4.0cm-1

FIGURE 35 - form

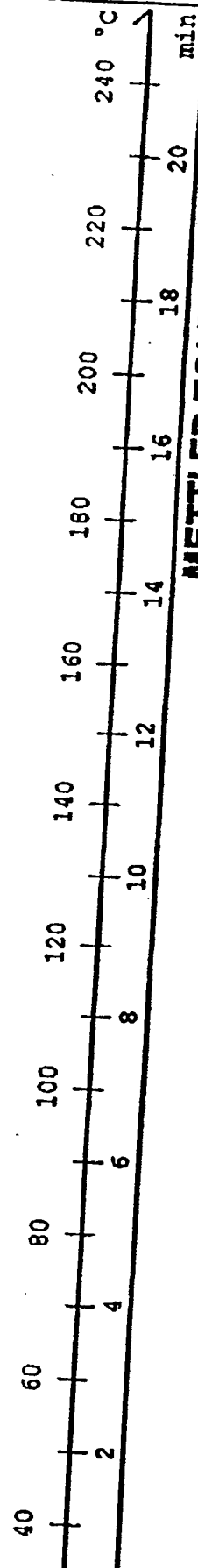


DRIFT, 4000-400CM-1, 16 SCANS RESOLUTION: 4.0CM-1

form (O)

FIGURE 36  
Form A

Method: 30-250°C, 10°C/min, 40ml/min N<sub>2</sub>  
30.0-250.0°C 10.00°C/min N<sub>2</sub>, 40.0 ml/min



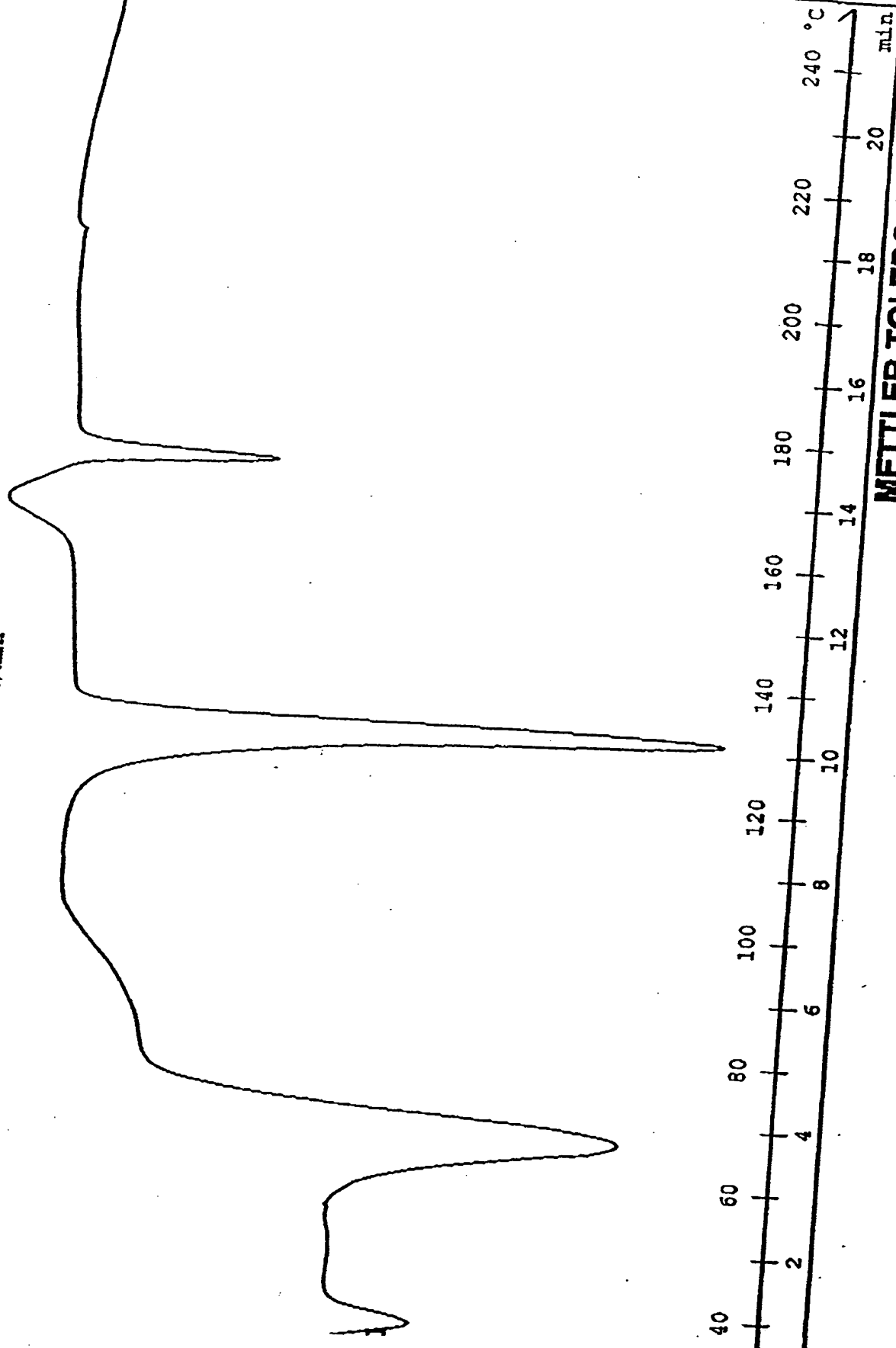
METTLER TOLEDO STAR® System

FIGURE 37

Form D

Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min



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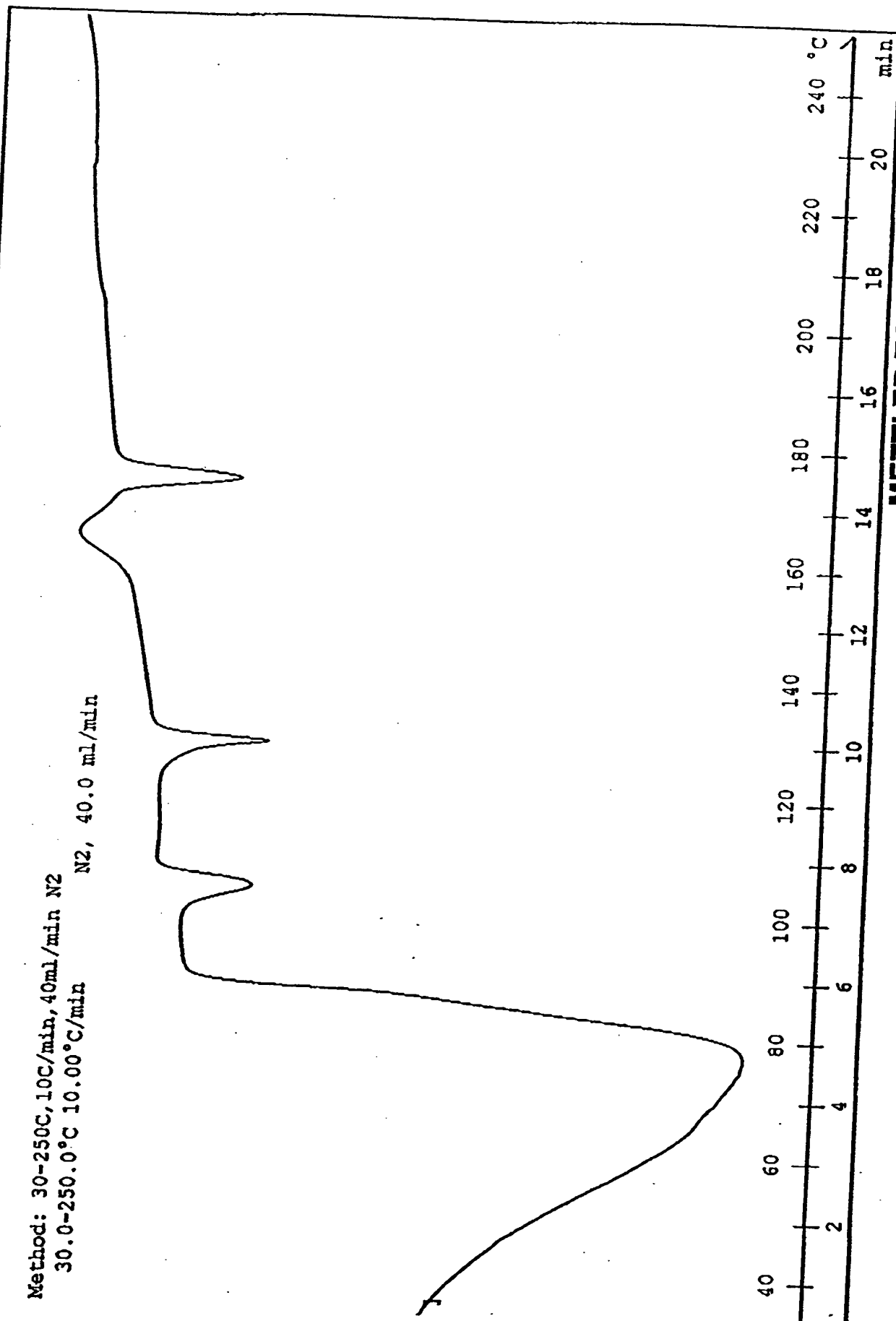
FIGURE 38

Form E

Method: 30-250C, 10C/min, 40ml/min N2

30.0-250.0°C 10.00°C/min

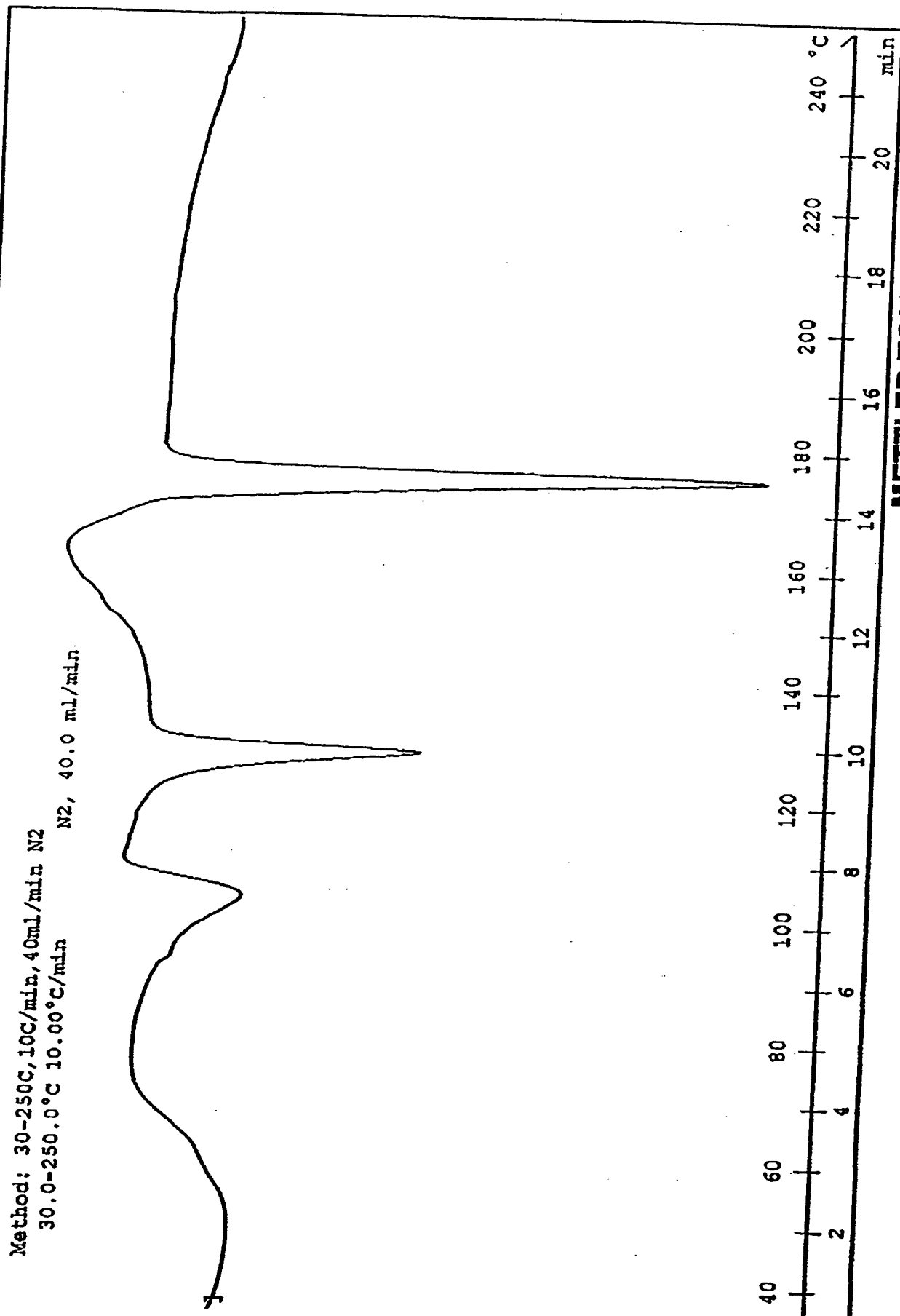
N2, 40.0 ml/min



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FIGURE 1



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40  
FIGURE 03

IXO

Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min N2, 40.0 ml/min

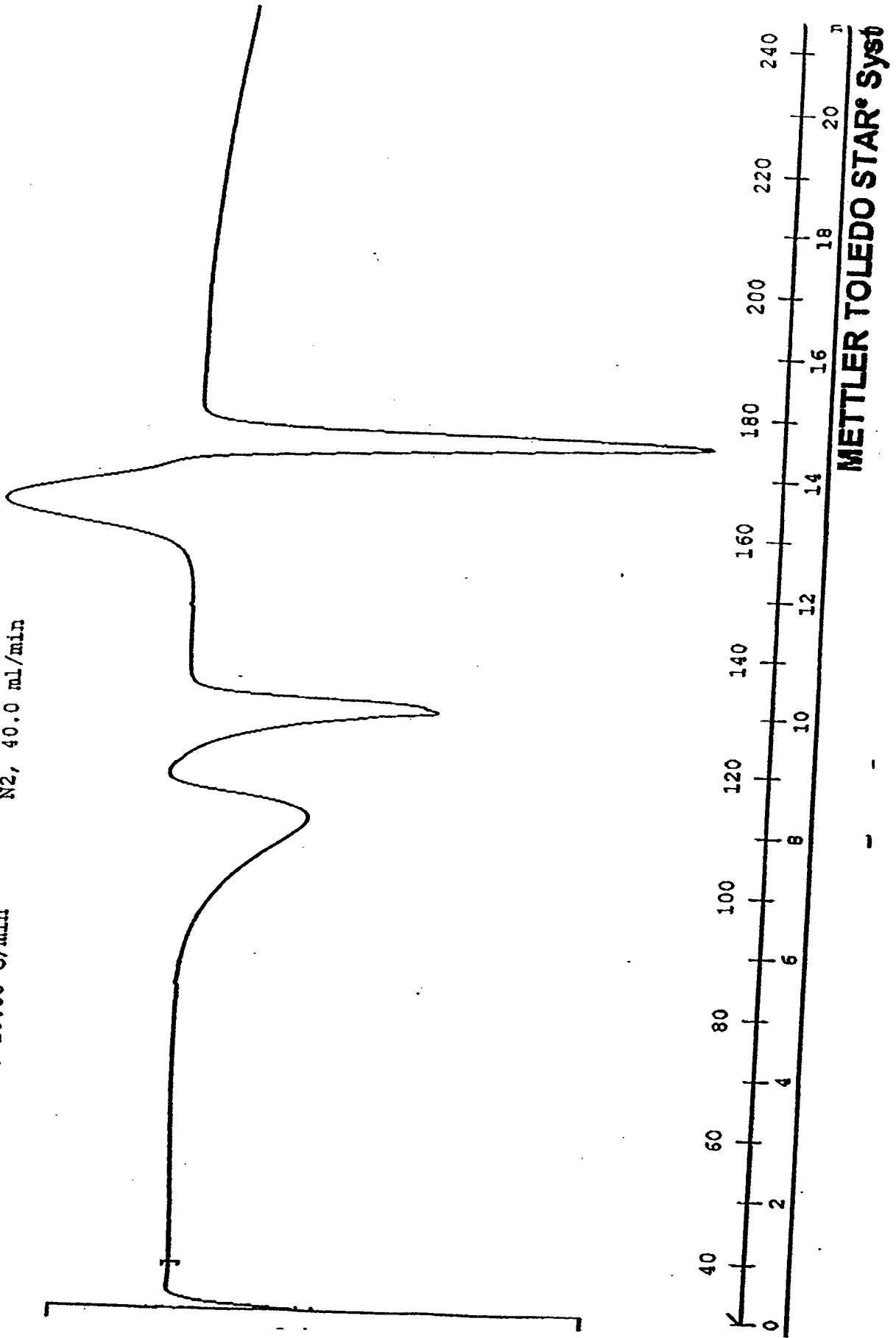
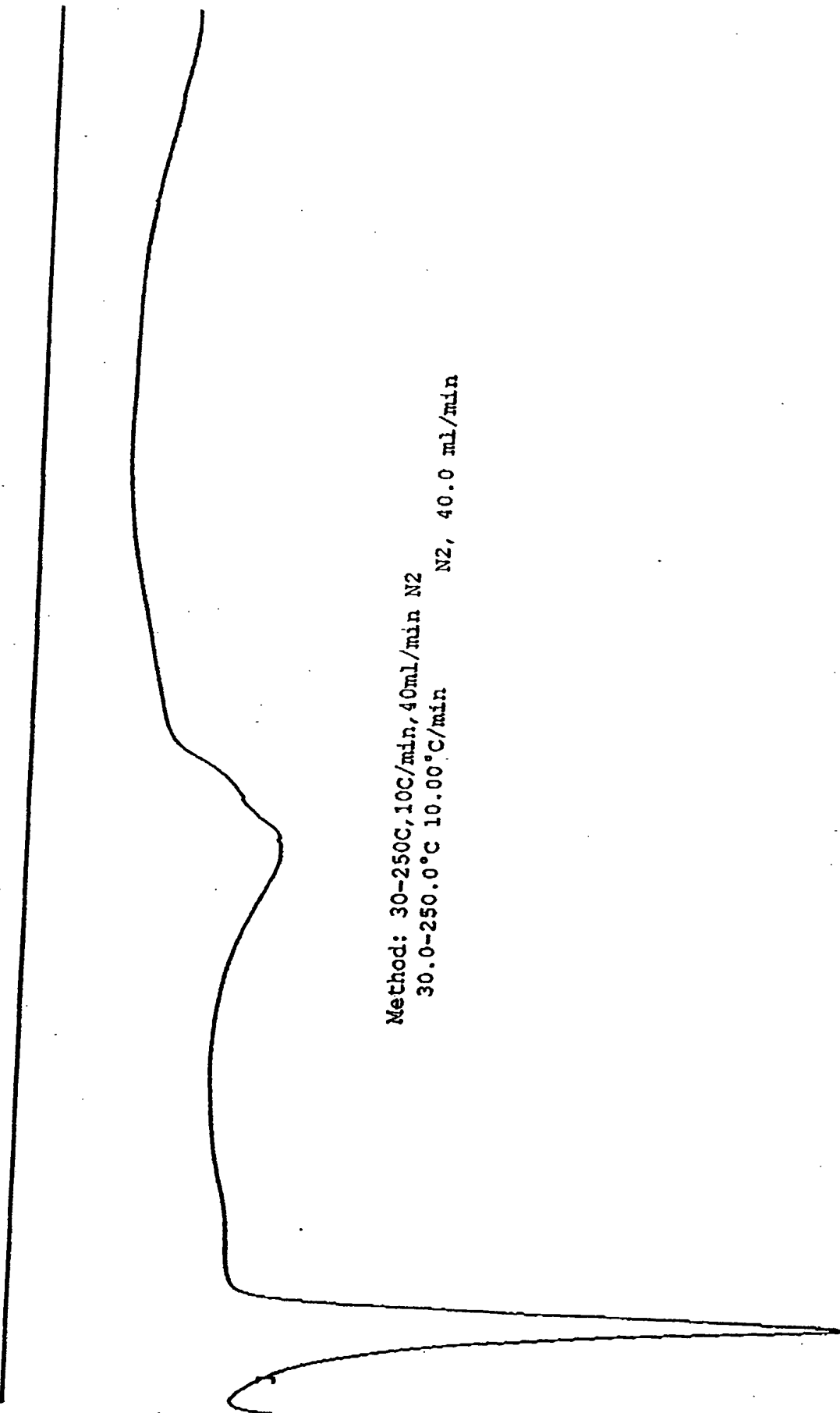
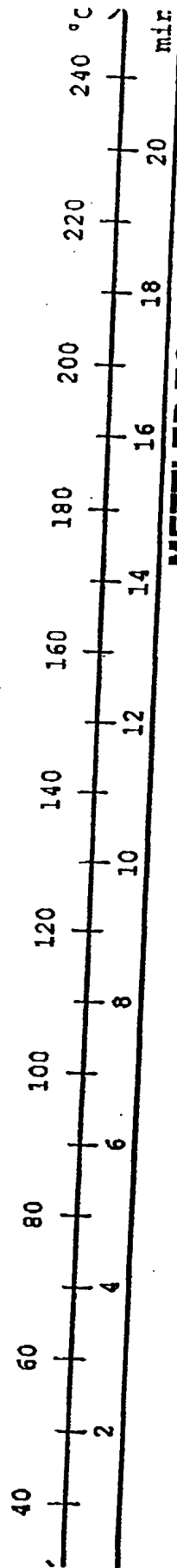


FIGURE 2041

Form I



Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min  
N2, 40.0 ml/min



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FIGURE 4d

Form J

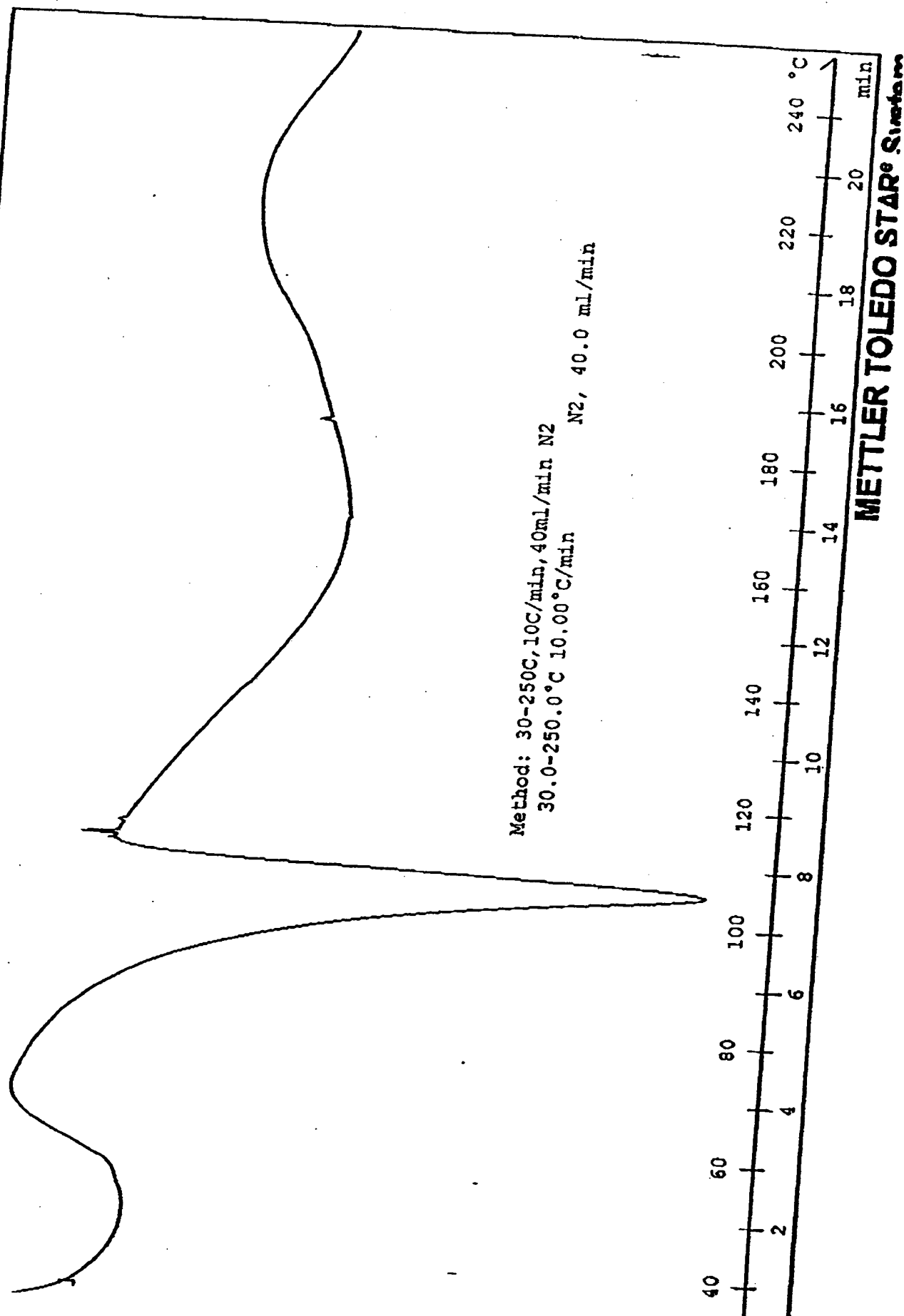


FIGURE 43  
Form K

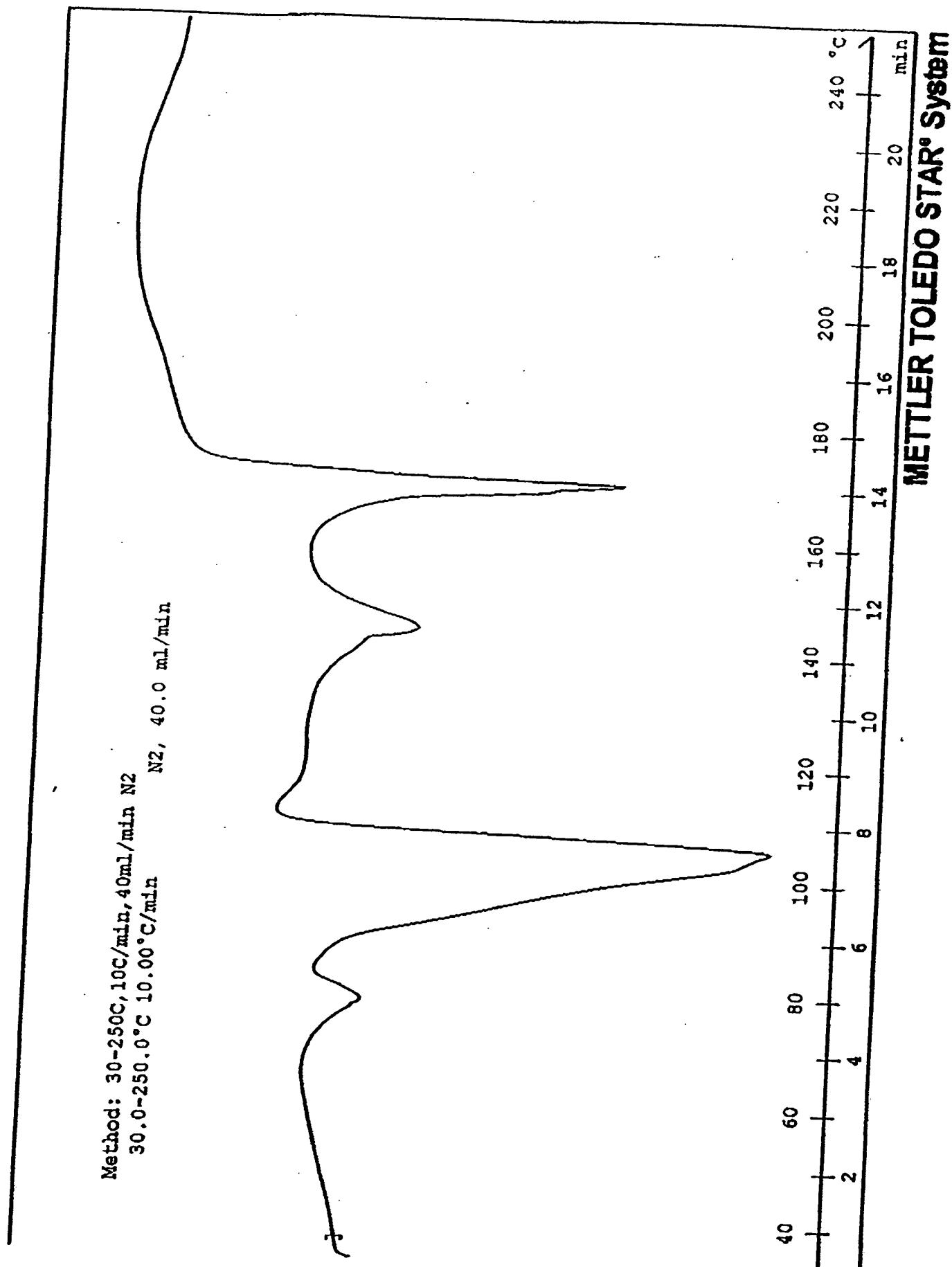


FIGURE 42  
4/4  
Form L

Method: 30-250°C, 10°C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min

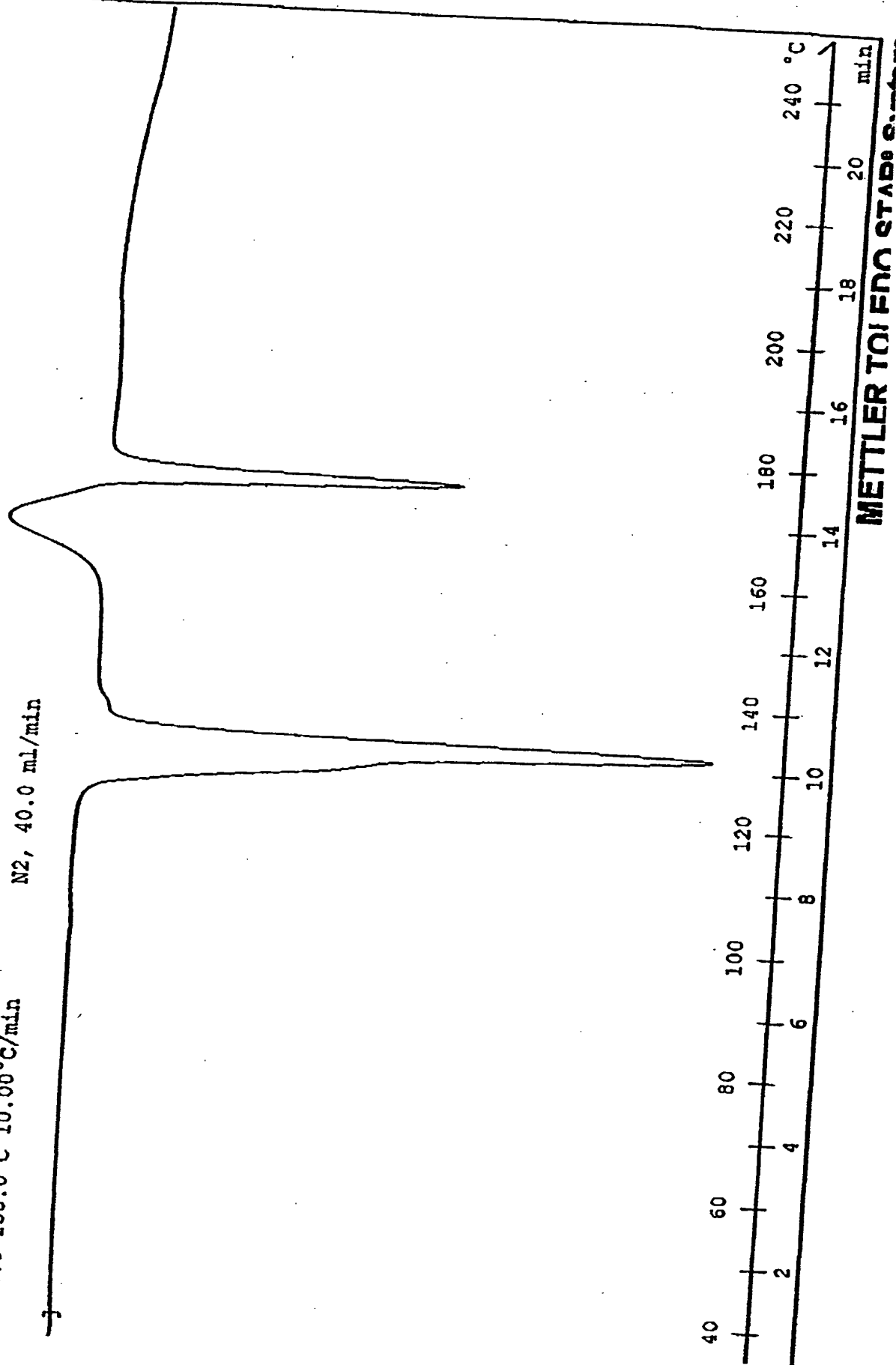
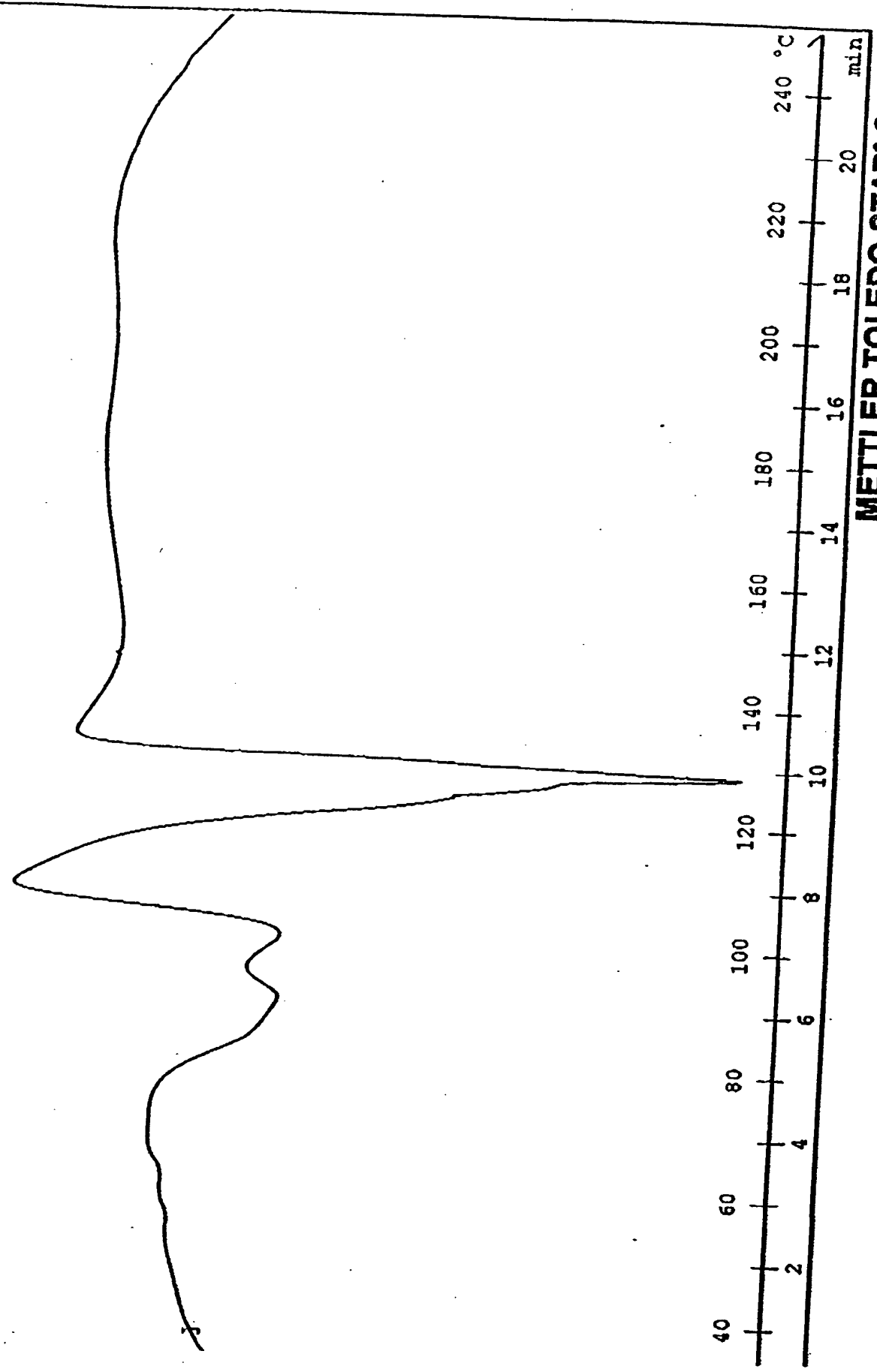


FIGURE 45  
Form M

Method: 30-250°C, 10°C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min N2, 40.0 ml/min



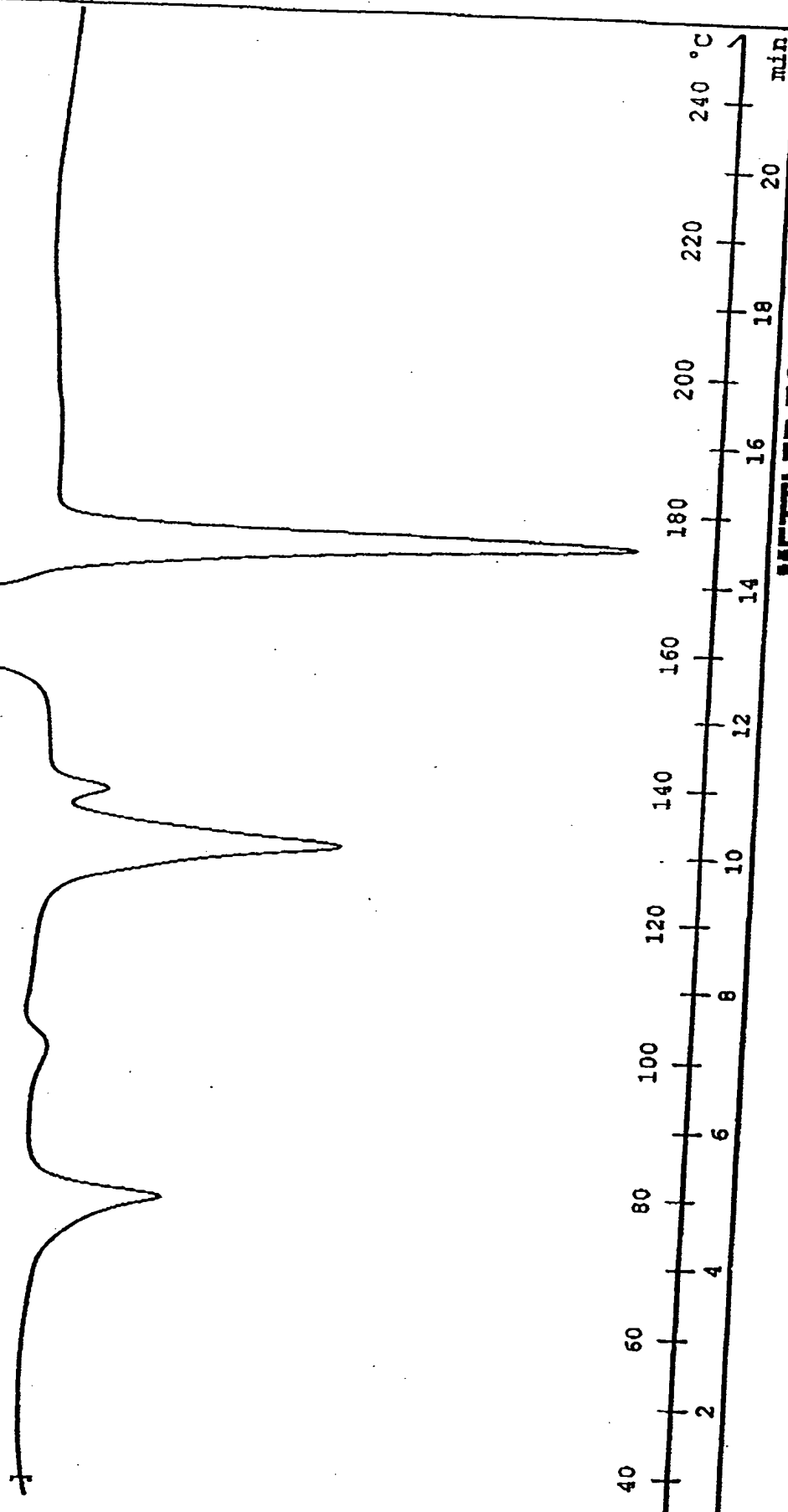
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FIGURE 44 4/6

Form N

Method: 30-250°C, 10°C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min



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FIGURE 45 47  
Form C

Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min

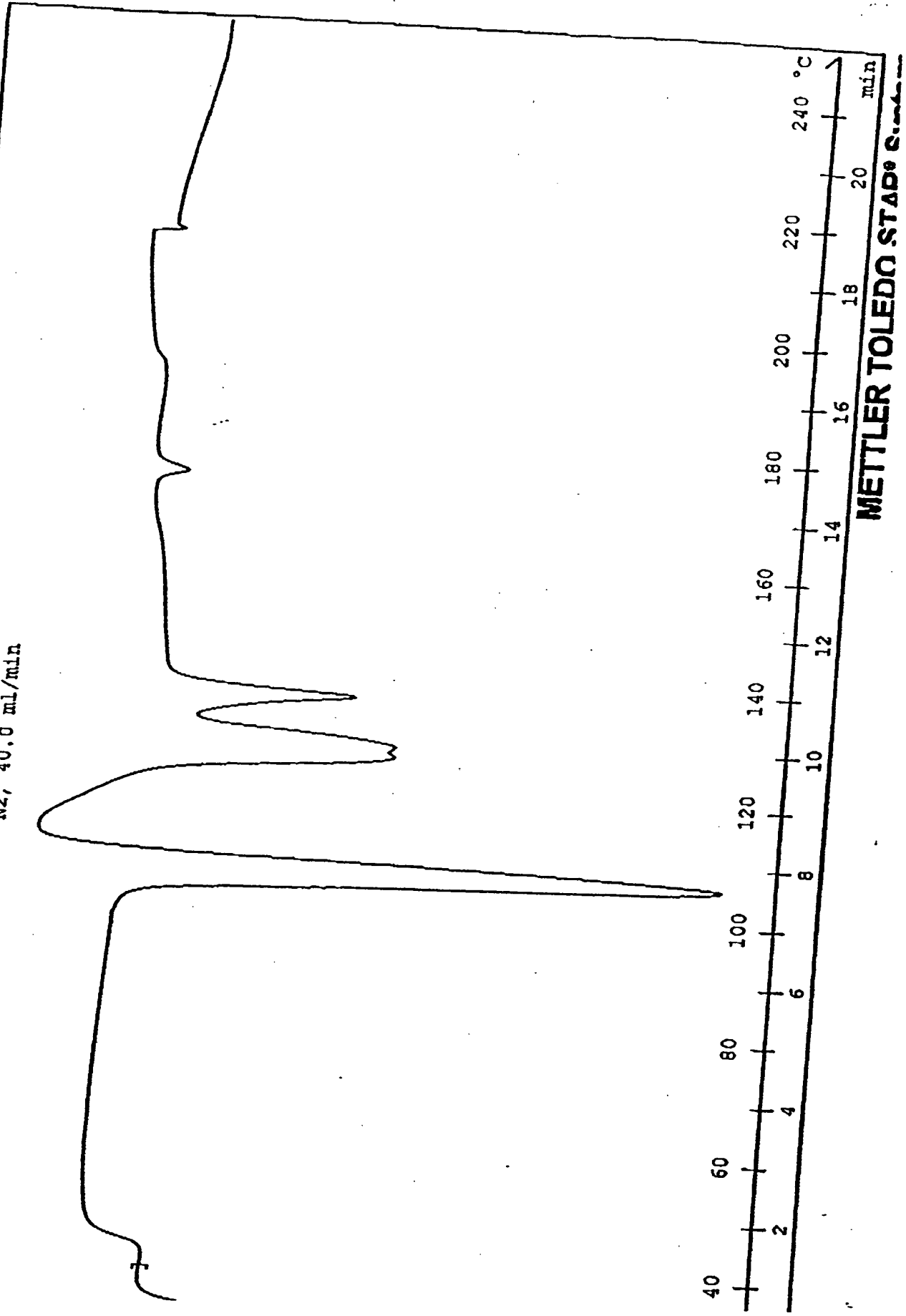
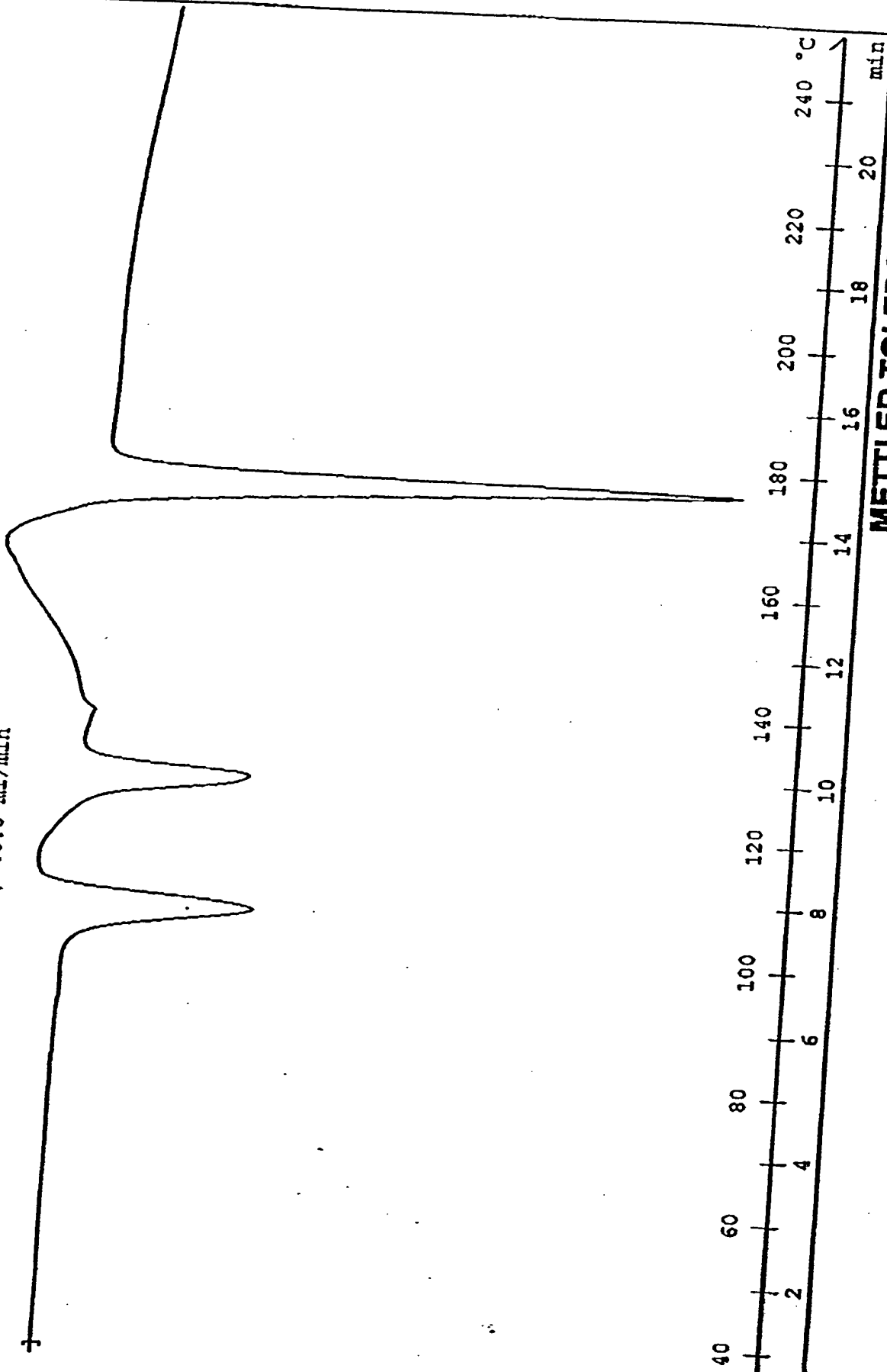




FIGURE 48  
Form P

Method: 30-250°C, 10°C/min, 40 mL/min N<sub>2</sub>  
30.0-250.0°C 10.00°C/min

N<sub>2</sub>, 40.0 mL/min



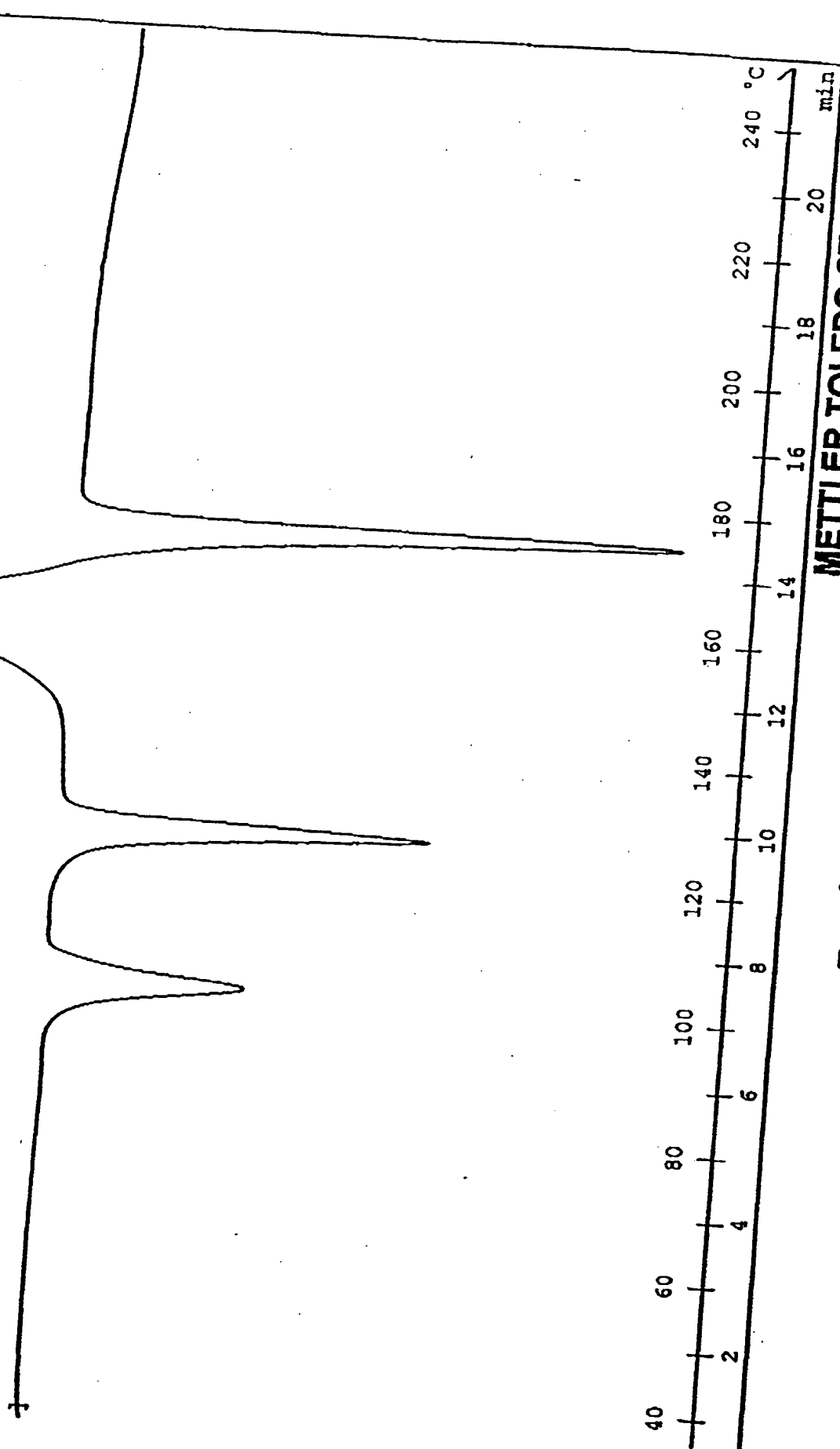
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FIGURE 47 49

Form Q

Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min

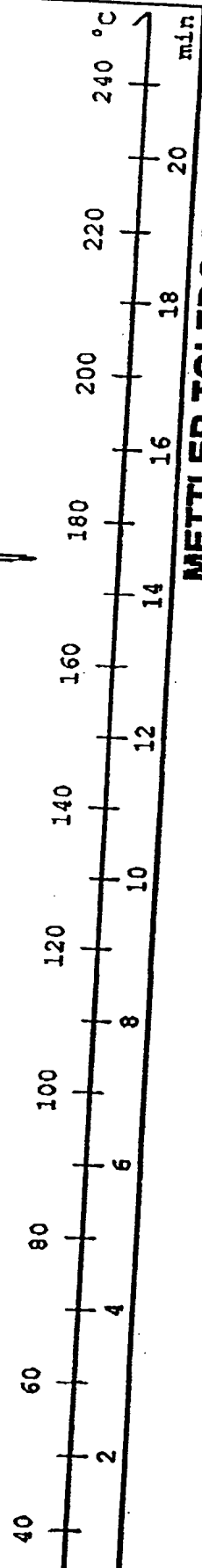
N2, 40.0 ml/min



METTTLER TOLEDO STAR® System

FIGURE 48-50  
Form T

Method: 30-250°C, 10°C/min, 40 mL/min N<sub>2</sub>  
30.0-250.0°C 10.00°C/min N<sub>2</sub>, 40.0 mL/min



METTLER TOLEDO STAR® System

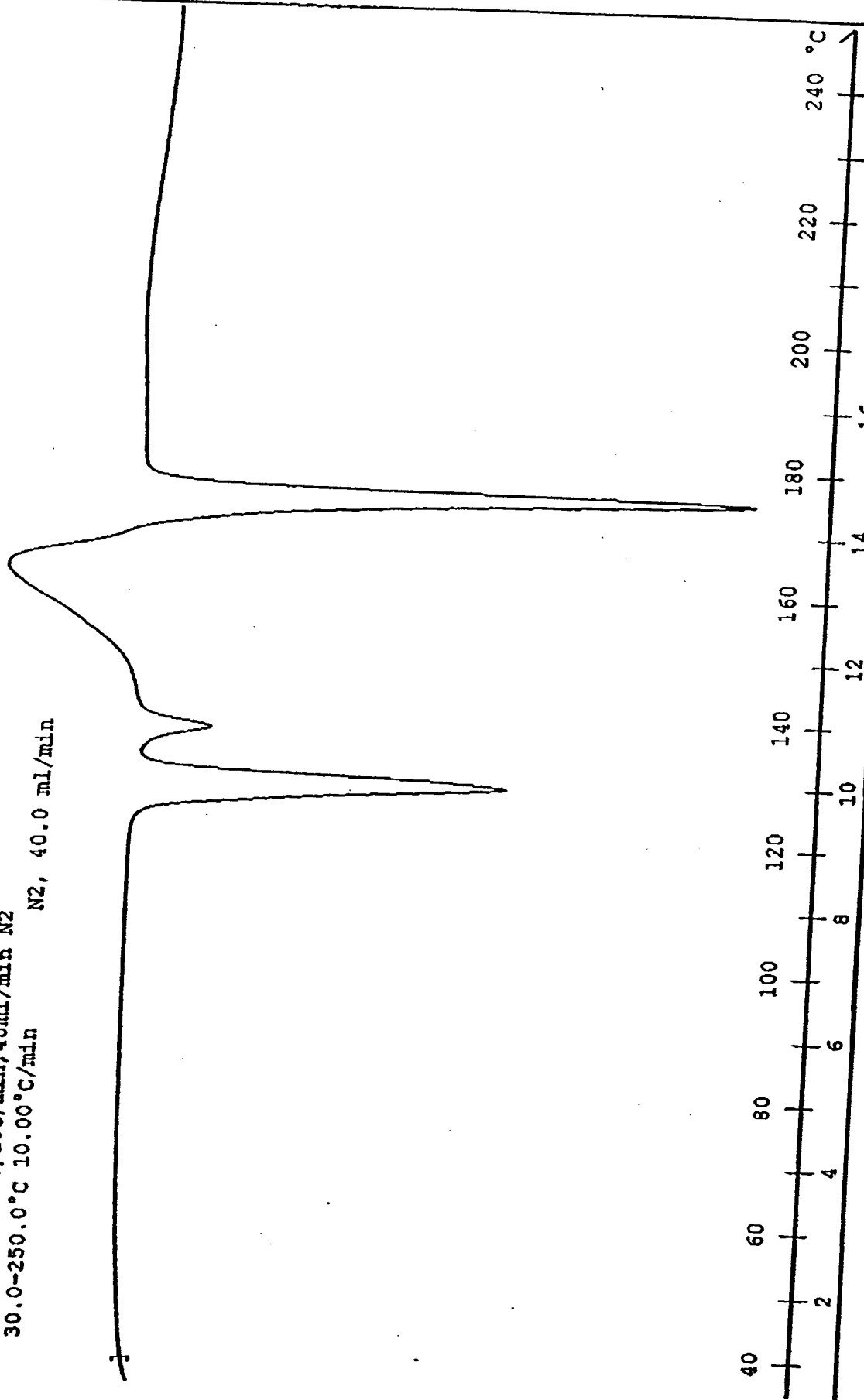
FIGURE 49. 51

Form 1A

Method: 30-250°C, 10°C/min, 40 ml/min N<sub>2</sub>

30.0-250.0°C 10.00°C/min

N<sub>2</sub>, 40.0 ml/min

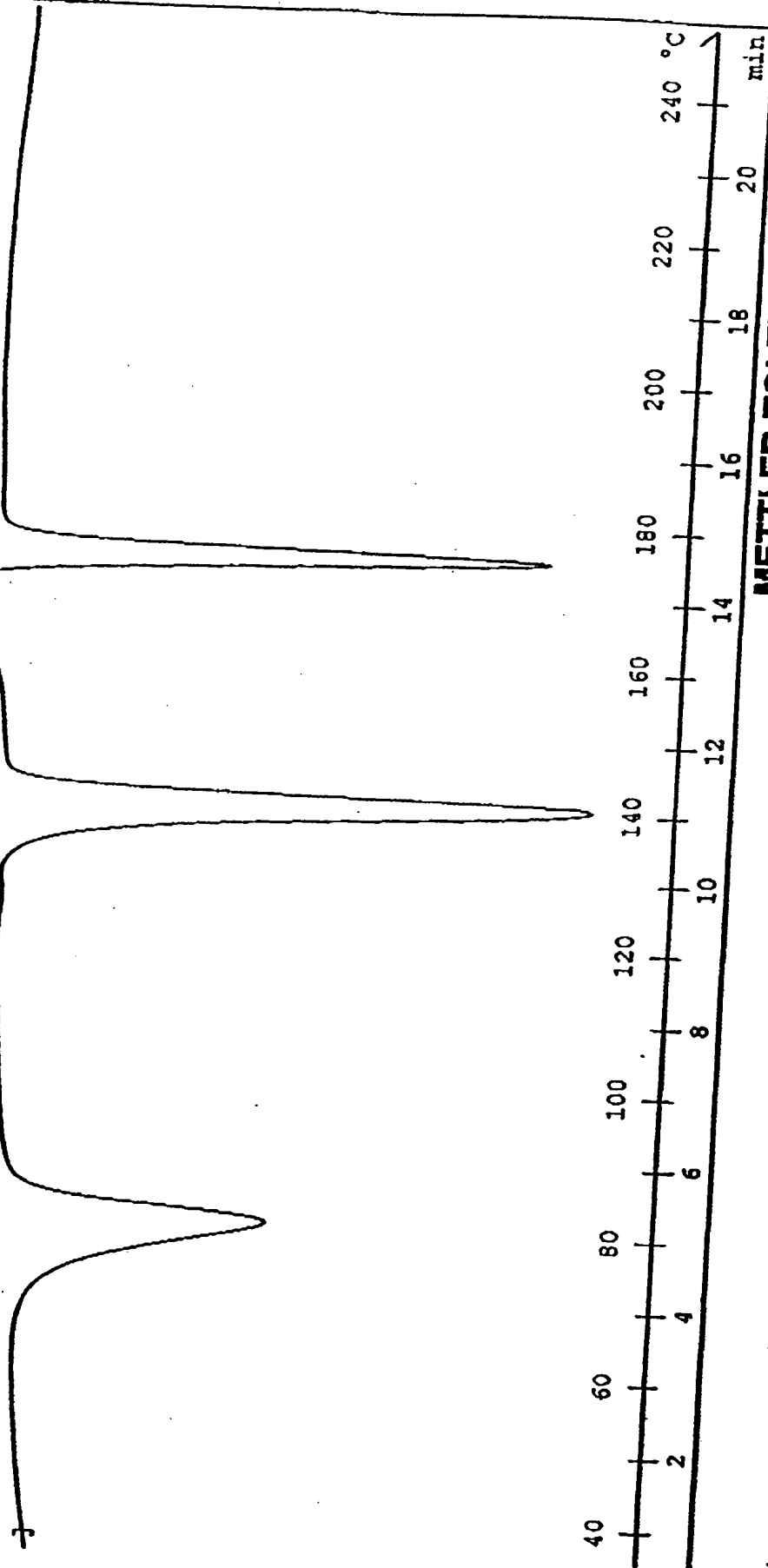


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FIGURE 5052  
Form V

Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min

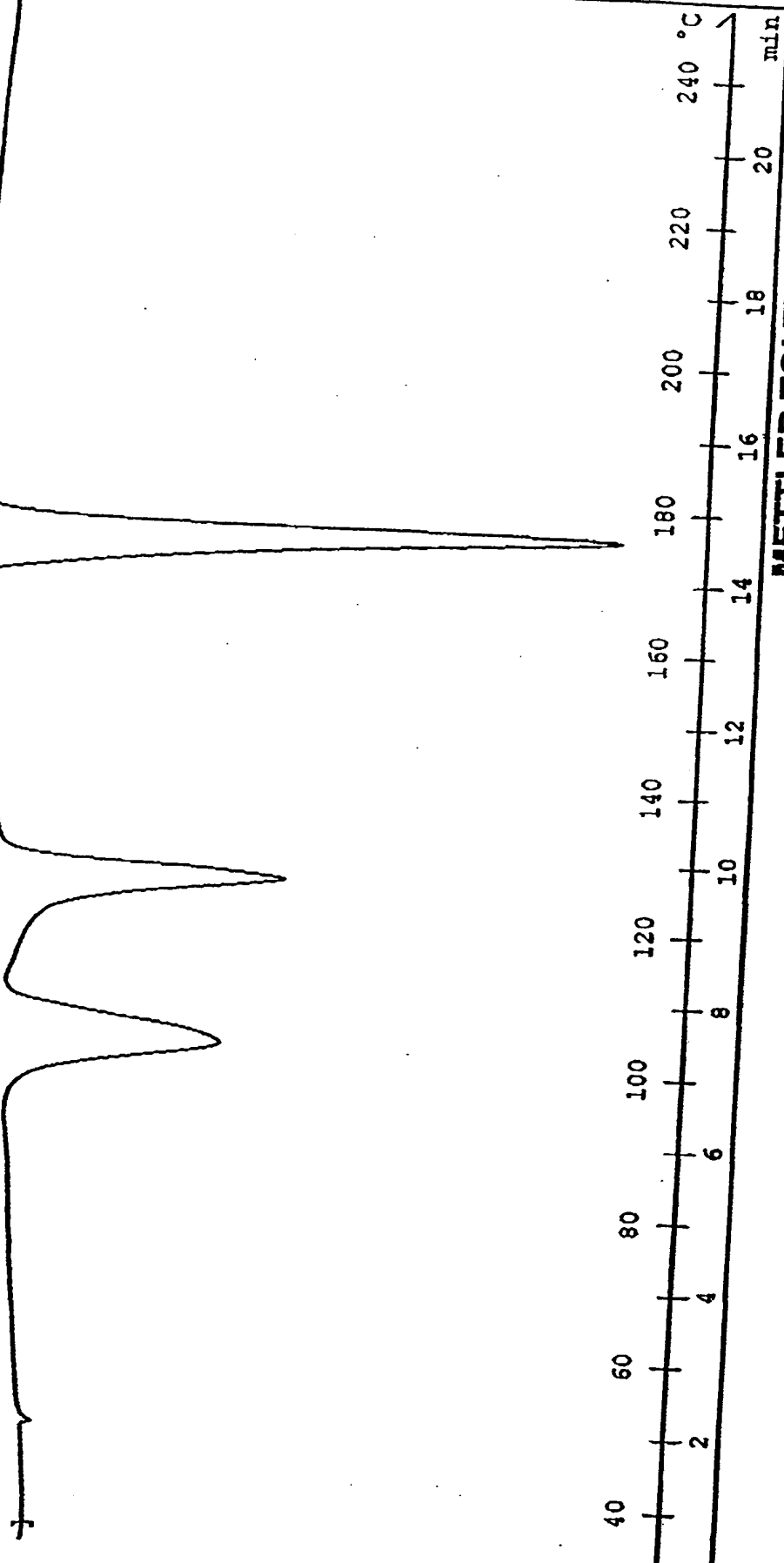
N2, 40.0 ml/min



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FIGURE 52-53  
Form Y (chloroform solvent)

Method: 30-250°C, 10°C/min, 40 ml/min N2  
30.0-250.0°C 10.00°C/min  
N2, 40.0 ml/min

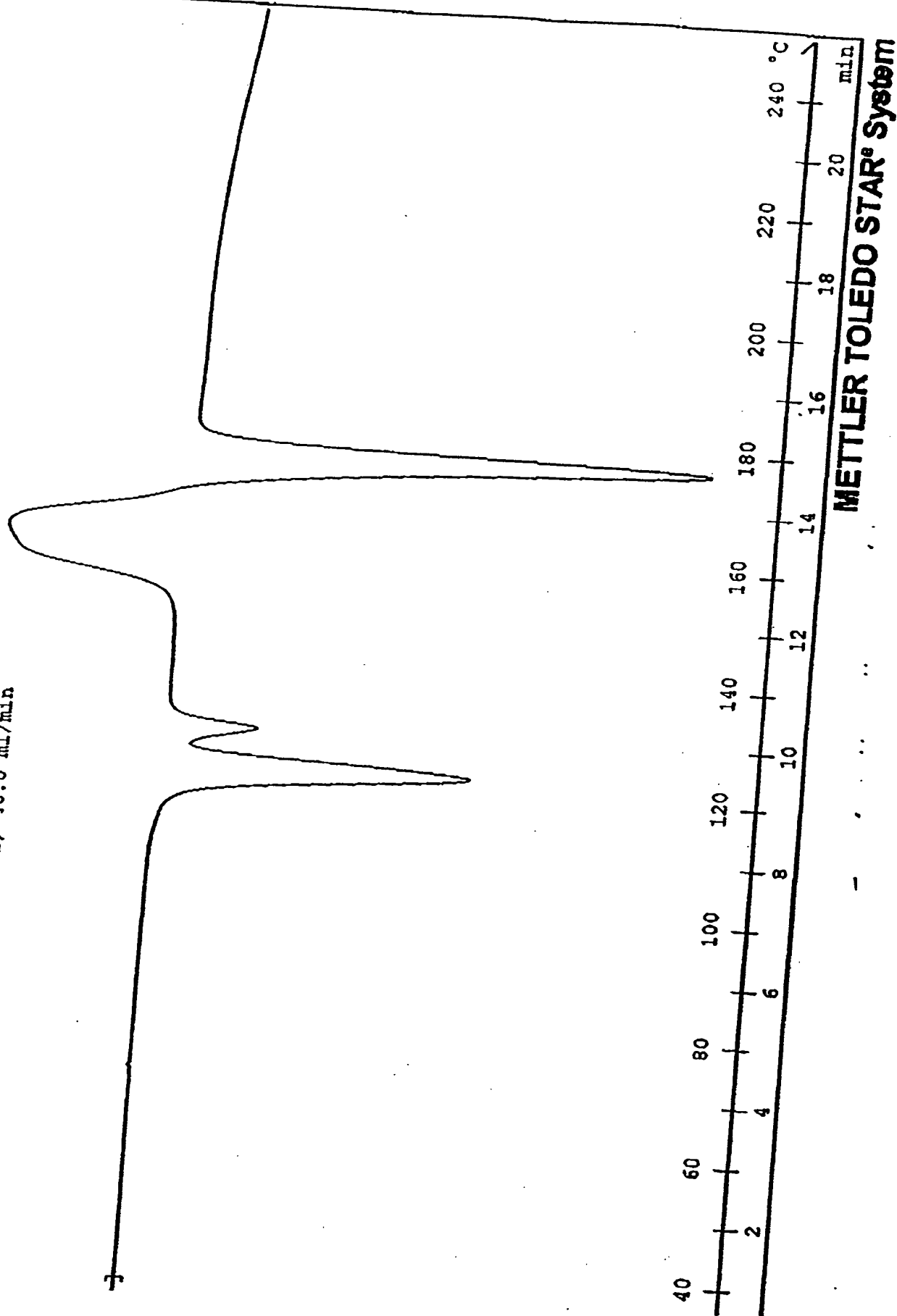


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FIGURE 5.4  
Y (dichloromethane solvate)

Method: 30-250°C, 10°C/min, 40 mL/min N<sub>2</sub>  
30.0-250.0°C 10.00°C/min

N<sub>2</sub>, 40.0 mL/min



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Figure 27 - Nateglinide Form Z

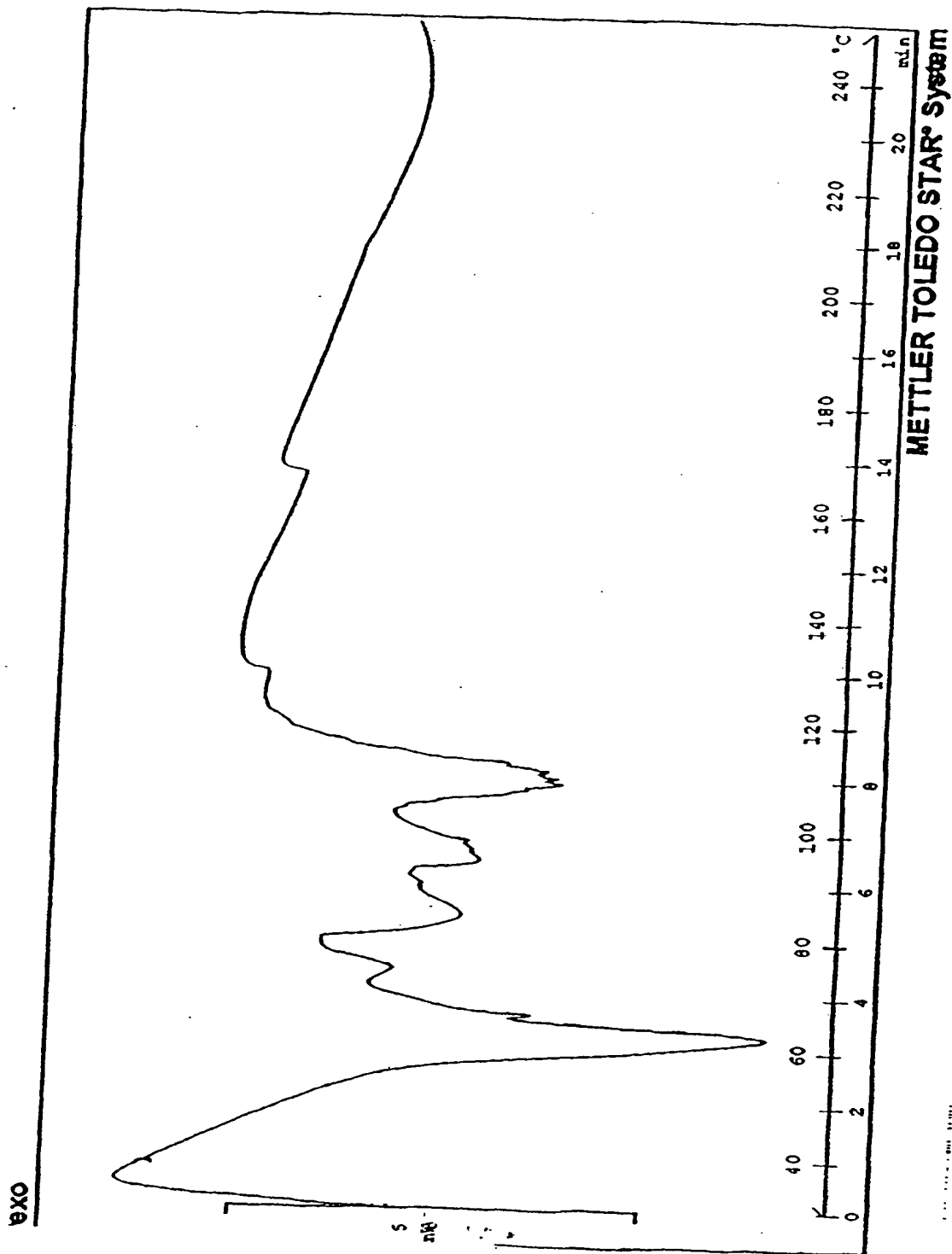
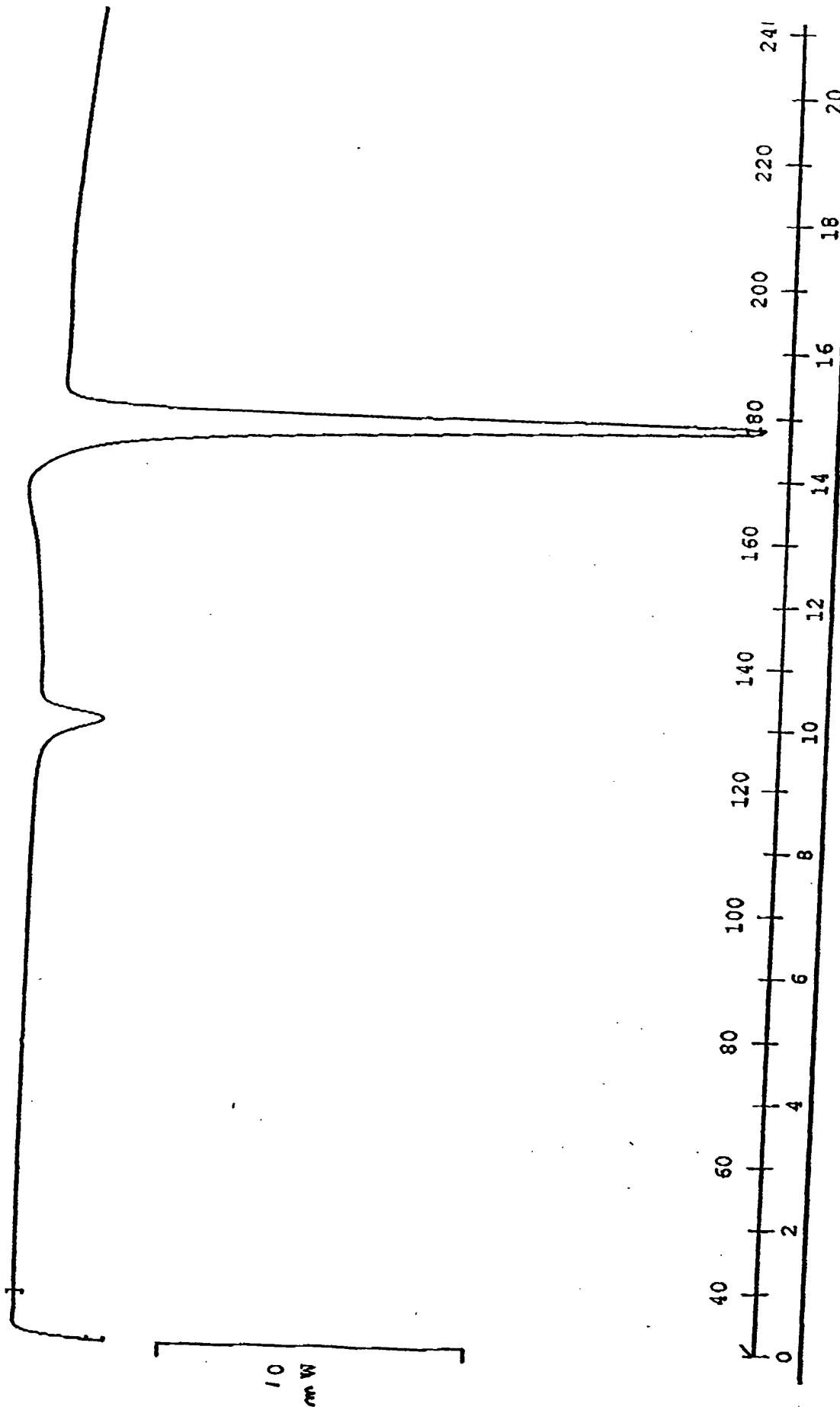




FIGURE 51-56  
Form  $\alpha$

IXO

Method: 30-250°C, 10°C/min, 40 ml/min N<sub>2</sub>  
30.0-250.0°C 10.00°C/min N<sub>2</sub>, 40.0 ml/min

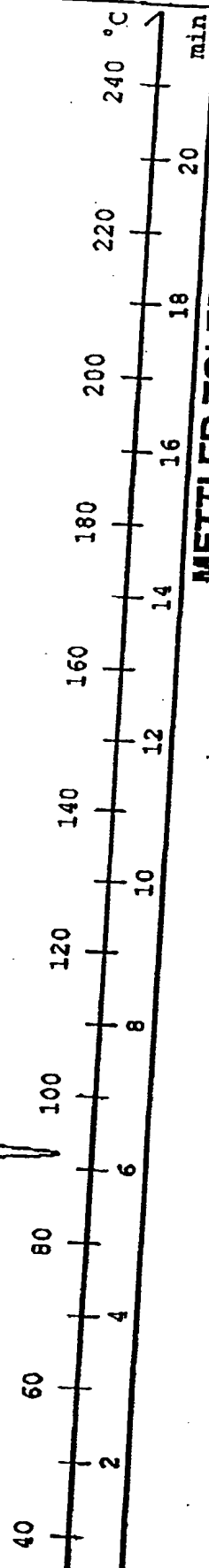


METTLER TOLEDO STAR° SW

FIGURE 57  
Form Beta

Method: 30-250°C, 10°C/min, 40 ml/min N<sub>2</sub>  
30.0-250.0°C 10.00°C/min

N<sub>2</sub>, 40.0 ml/min

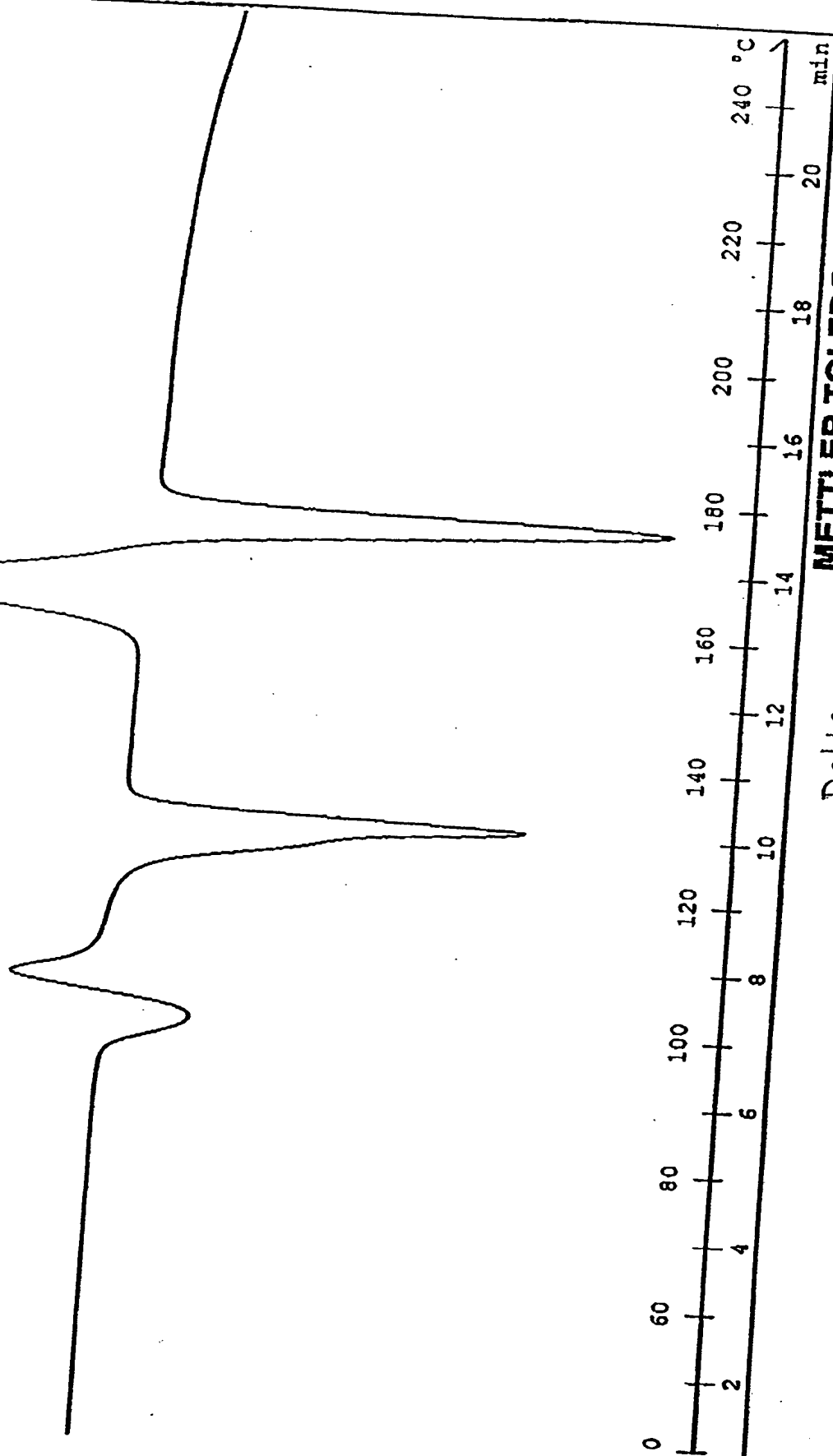


METTLER TOLEDO STAR® System

FIGURE 55-58  
Form Delta

Method: 30-250°C, 10°C/min, 40 mL/min N<sub>2</sub>  
30.0-250.0°C 10.00°C/min

N<sub>2</sub>, 40.0 mL/min



METTLER TOLEDO STAR® System

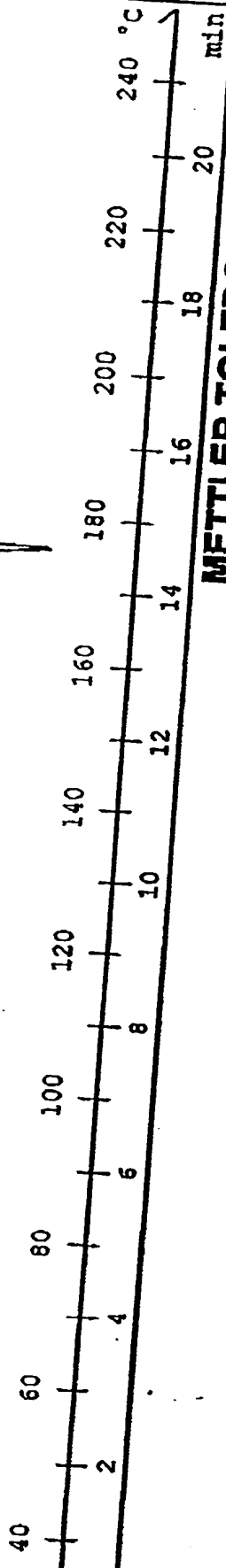
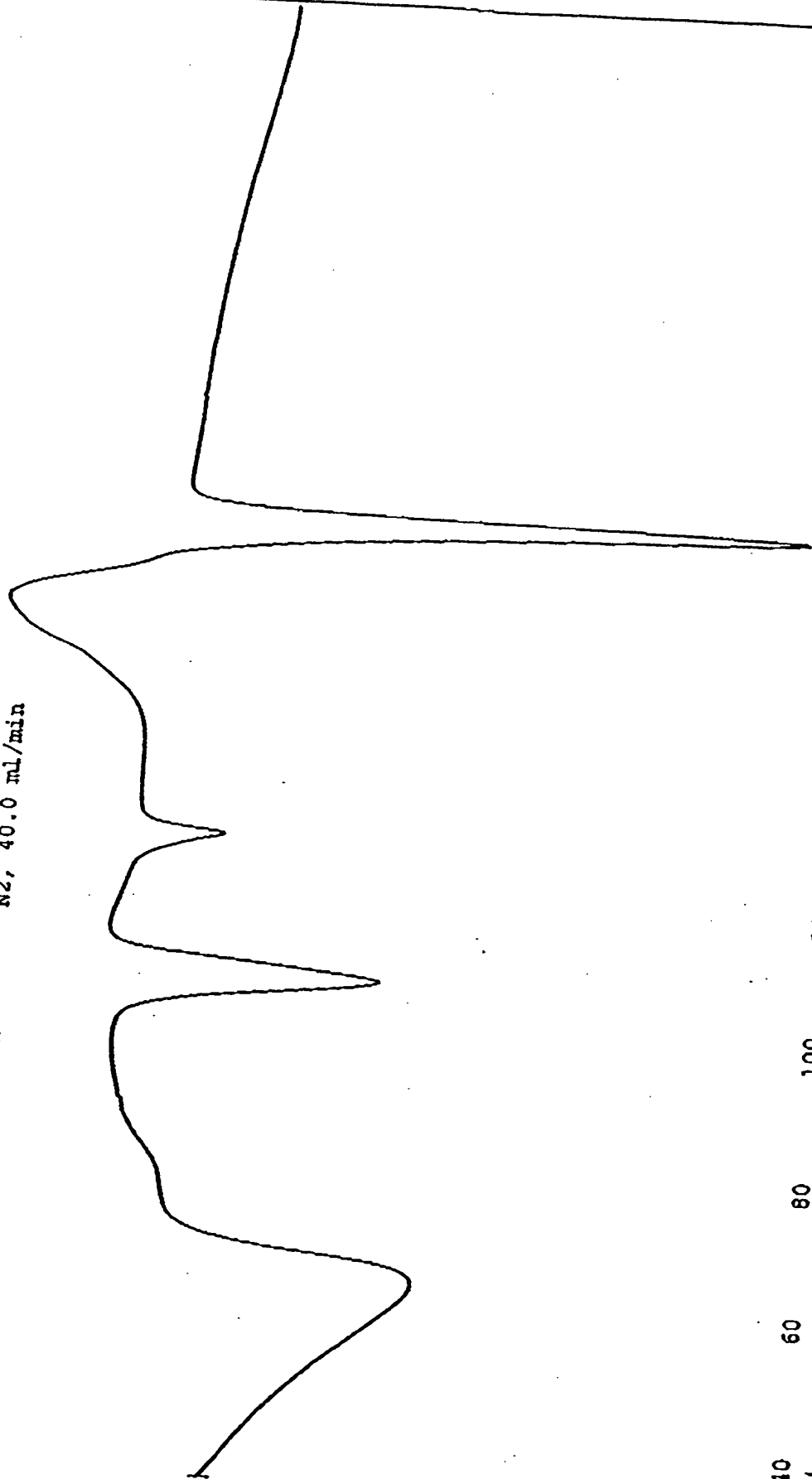
- Delta

Form Epsilon

FIGURE 59

Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min

N2, 40.0 ml/min

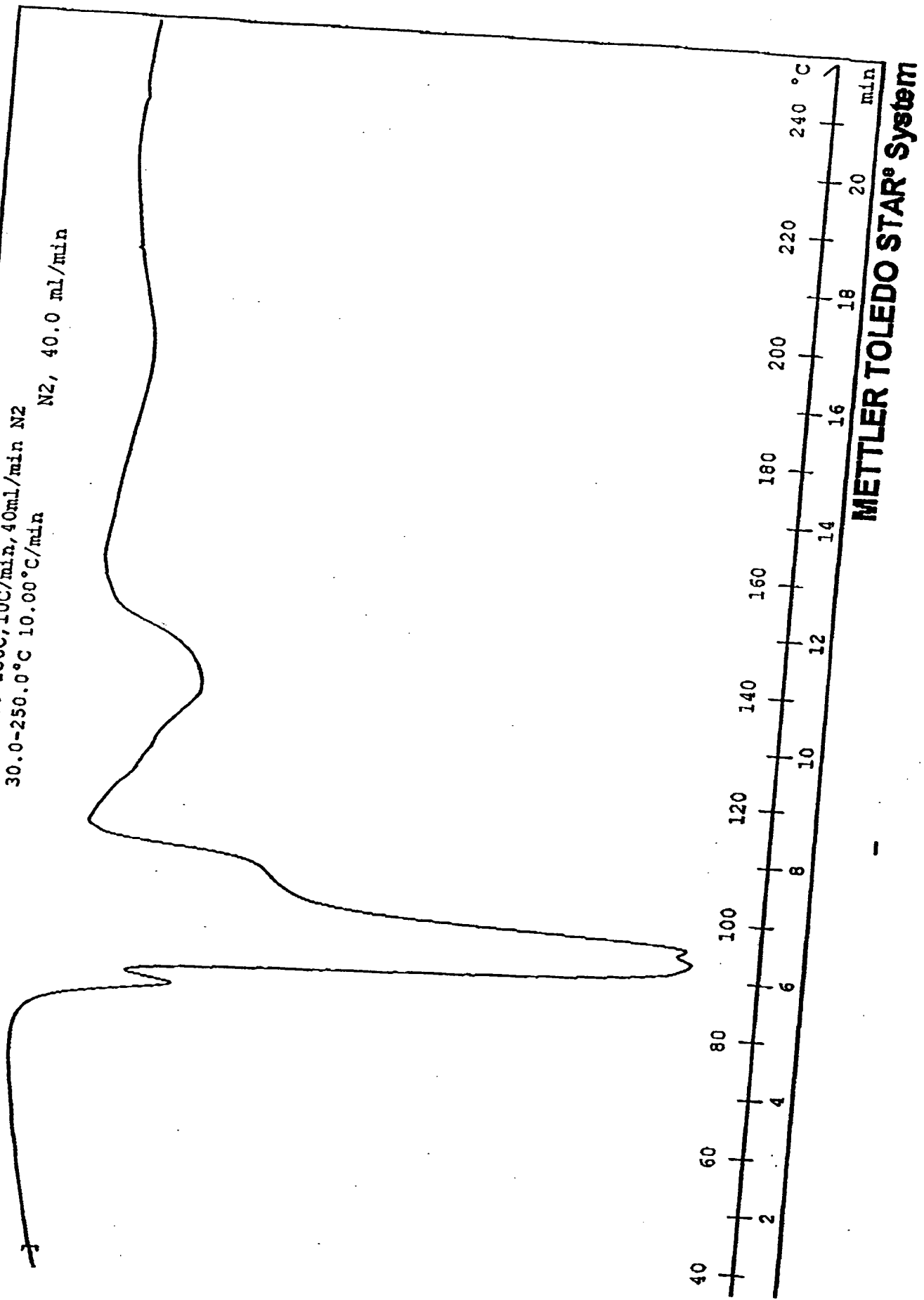


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FIGURE 57 <sup>60</sup>

Form ~~P~~ Gamma

Method: 30-250C, 10C/min, 40ml/min N2  
30.0-250.0°C 10.00°C/min N2, 40.0 ml/min

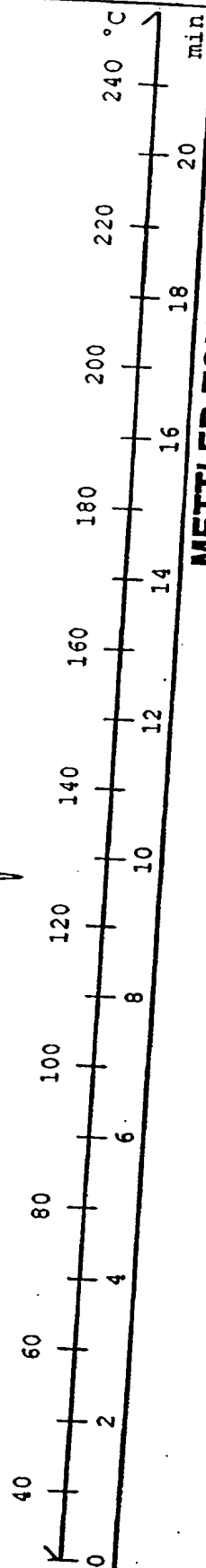


METTLER TOLEDO STAR® System

FIGURE 01 Form Sigma

Exo

10  
mW

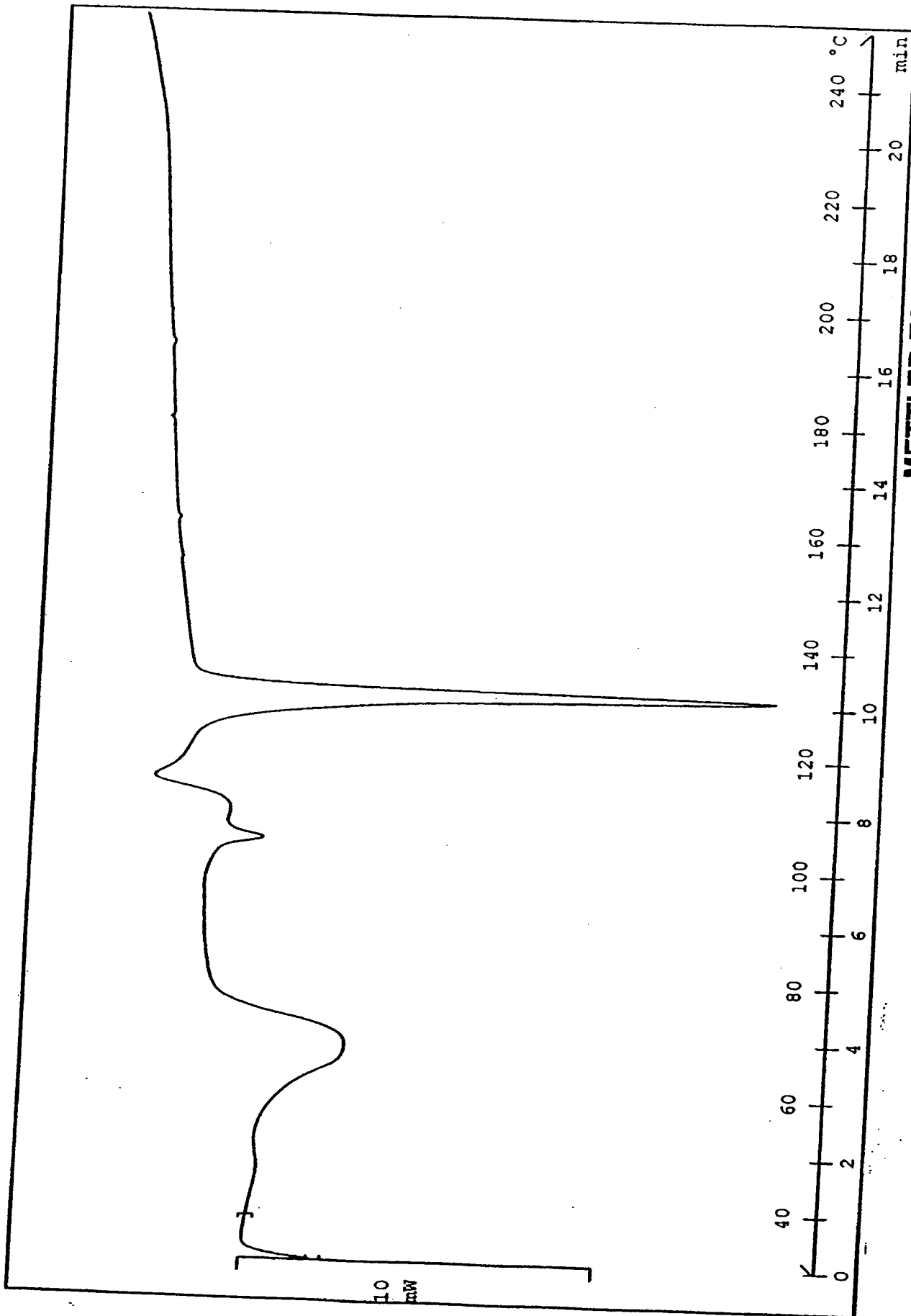


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Form 01 (05)

FIGURE 52-62 Form Theta

Exo



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Form 8

Figure 03

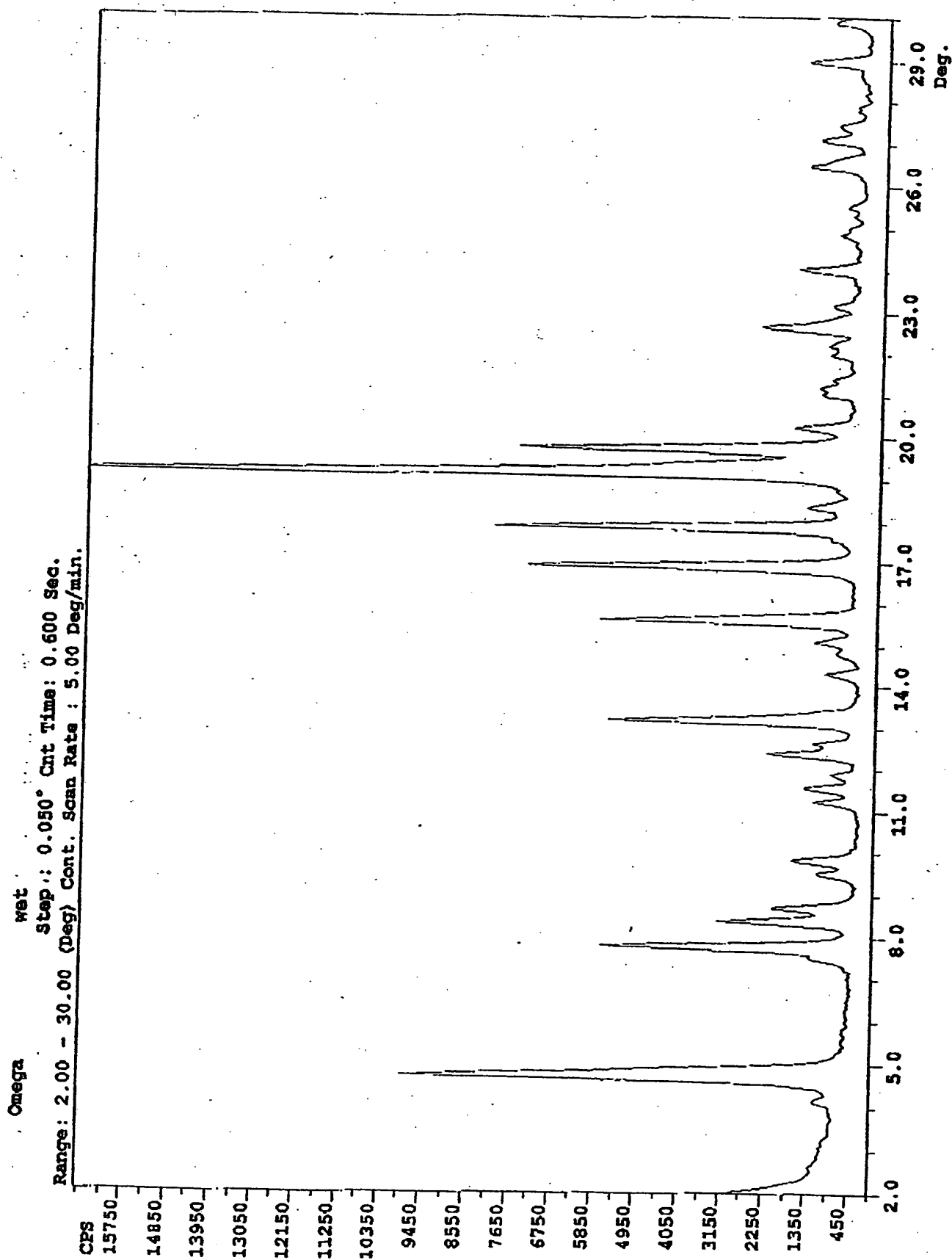




Figure 64

Comparison between the impurity profile of Nateglinide crystallized in IPA-H<sub>2</sub>O and Nateglinide crystallized in Methanol-H<sub>2</sub>O

Sample No	Solvent	Impurity profile by RRT [% w/w]						
		D-PA (0.23)	(0.25)	(0.46)	(0.80)	Ipcha (0.89)	Dimer (1.38)	Methyl Ester (1.51)
RL-2155/1	Methanol-H <sub>2</sub> O	<0.01		0.02	<0.01	0.03	0.02	2.91
RL-2163/4	IPA-H <sub>2</sub> O	<0.01	0.04		0.02	0.02	0.01	0.04
								0.03
								0.02

Note: D-PA means D-Phenyl Alanine

Ipcha means Iso propyl cyclohexyl carboxylic acid

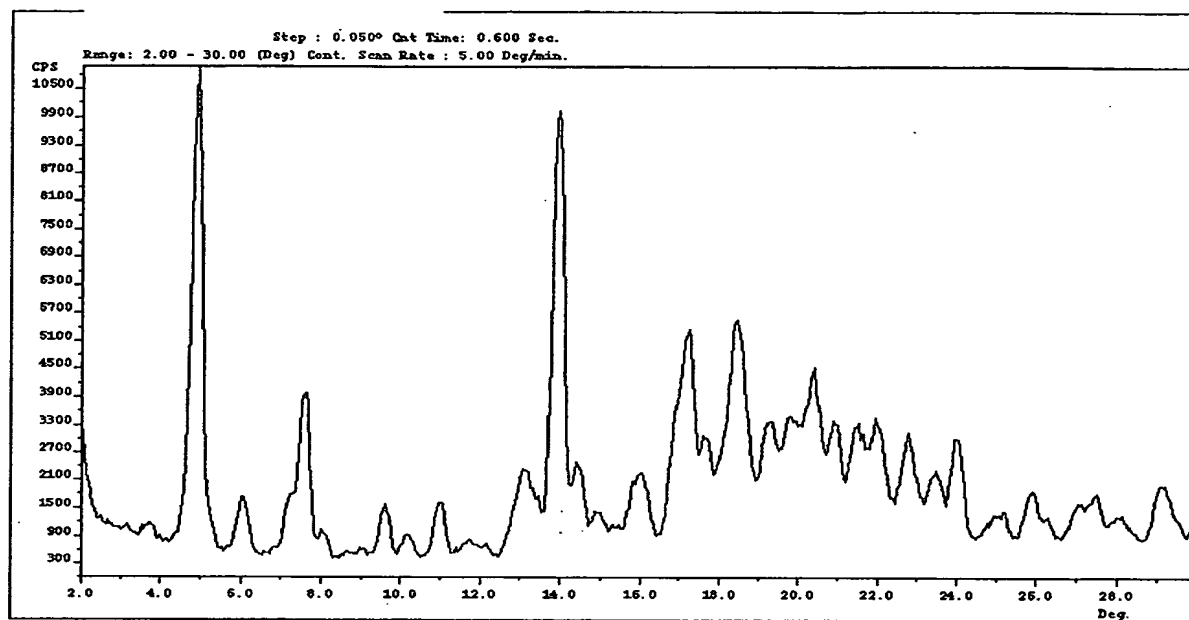
Both are the starting materials of the product

(-)-N-[(trans-4-isopropyl cyclohexane)carbonyl]-D-phenylalanine

Newly Added

**Figure 65**

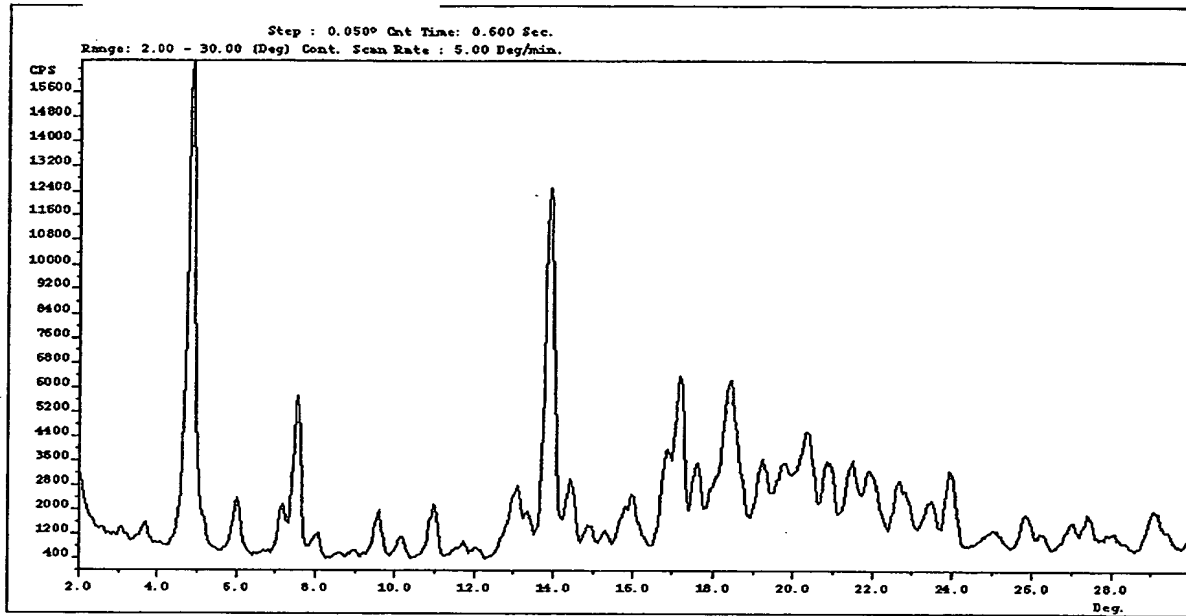
Form U- Crystallization in Ethyl-Acetate – drying at 30°C- Sample prepared according to Example 17,



Newly Added.

**Figure 66**

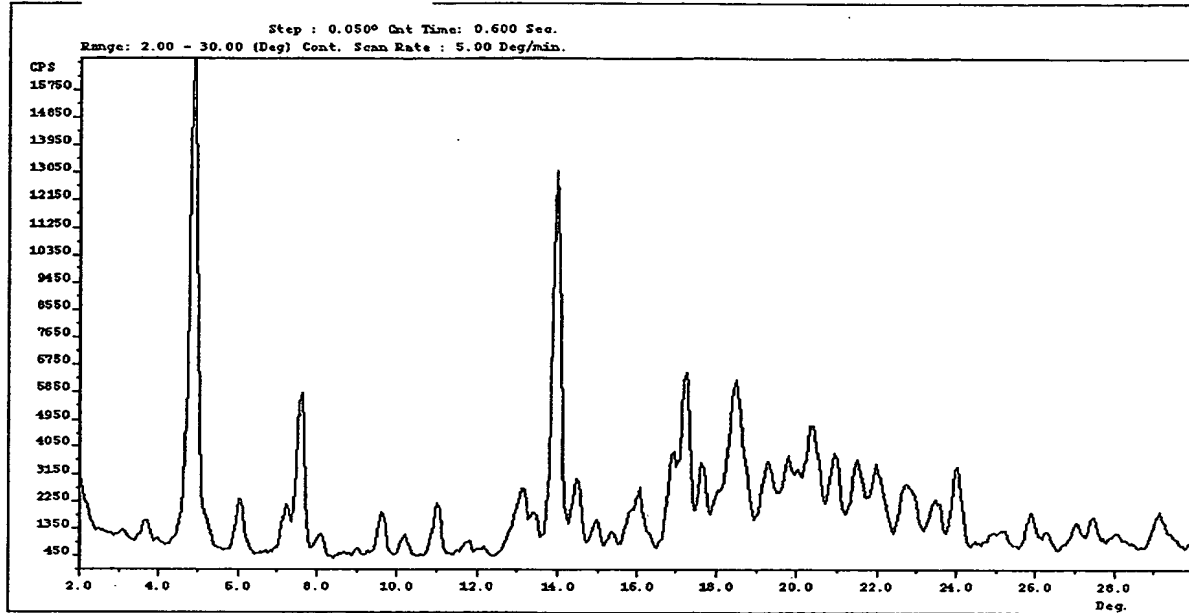
Form U- Crystallization in Ethyl-Acetate – drying at 50°C - Sample prepared according to Example 17.



Newly Added.

Figure 67

Form U- Crystallization in Ethyl-Acetate – drying at 90°C - Sample prepared according to Example 17.



Newly Added.

**Figure 68**

Form U- Crystallization in Acetone - Sample prepared according to Example 17.

